Section	Field Name	Туре	Description
Event	adverse_event_flag	string	Whether the report is about an incident where the use of the device is suspected to have resulted in an adverse outcome in a patient.
ı			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			Y = Yes
			N = No
Event	product_problems	array of strings	The product problems that were reported to the FDA if there was a concern about the quality, authenticity, performance, or safety of any medication or device.
Event	product_problem_flag	string	Indicates whether or not a report was about the quality, performance or safety of a device.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			Y = The report is about the quality, performance, or safety of a device—for example, defects or malfunctions. This flag is set when a device malfunction could lead to a
			death or serious injury if the malfunction were to recur.
			N = The report is not about a defect or malfunction.
Event	date_of_event	string	Actual or best estimate of the date of first onset of the adverse event. This field was added in 2006.
Event	date_report	string	Date the initial reporter (whoever initially provided information to the user facility, manufacturer, or importer) provided the information about the event.
Event	date_received	string	Date the report was received by the FDA.
Event	device_date_of_manufacturer	string	Date of manufacture of the suspect medical device.
Event	event_type	string	Outcomes associated with the adverse event.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			Death = Death, either caused by or associated with the adverse event.
			Injury (IN) = Documentation forthcoming.
ı			Injury (IL) = Documentation forthcoming.
ı			Injury (IJ) = Documentation forthcoming.
ı			Malfunction = Product malfunction.
I			Other = Other serious/important medical event.
L .		1	No answer provided = No information was provided.
Event	number_devices_in_event	string	Number of devices noted in the adverse event report. Almost always 1. May be empty if report_source_code contains Voluntary report.
ı			L
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Event	number_patients_in_event	string	Number of patients noted in the adverse event report. Almost always 1. May be empty if report_source_code contains Voluntary report.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Event	previous_use_code	string	Whether the use of the suspect medical device was the initial use, reuse, or unknown.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			I = Initial use.
			R = Reuse.
			U = Unknown.
			* = Invalid data or this information was not provided.
Event	remedial_action	array of strings	Follow-up actions taken by the device manufacturer at the time of the report submission, if applicable.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			Recall = Recall
			Repair = Repair
			Replace = Replace
			Relabeling = Relabeling
			Other = Other
			Notification = Notification
			Inspection = Inspection
			Patient Monitoring = Patient Monitoring
			Modification/Adjustment = Modification/Adjustment
			Invalid Data = Invalid Data
Event	removal_correction_number	string	If a corrective action was reported to FDA under 21 USC 360i(f), the correction or removal reporting number (according to the format directed by 21 CFR 807). If a firm
			has not submitted a correction or removal report to the FDA, but the FDA has assigned a recall number to the corrective action, the recall number may be used.
ı			
ı			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
ı			
Event	report_number	string	Identifying number for the adverse event report. The format varies, according to the source of the report. The field is empty when a user facility submits a report. For
I			manufacturer reports. Manufacturer Report Number. The report number consists of three components: The manufacturer's FDA registration number for the
I			manufacturing site of the reported device, the 4-digit calendar year, and a consecutive 5-digit number for each report filed during the year by the manufacturer (e.g.
I			1234567-2013-00001, 1234567-2013-00002). For user facility/importer (distributor) reports. Distributor Report Number. Documentation forthcoming. For consumer
ı			reports. This field is empty.
I			I
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Event	single_use_flag	string	Whether the device was labeled for single use or not.
I			I
I			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
ı			
ı			Value is one of the following
ı			Yes = The device was labeled for single use.
L		1	No = The device was not labeled for single use, or this is irrelevant to the device being reported (e.g. an X-ray machine).
Source	report_source_code	string	Source of the adverse event report
ı			
ı			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
ı			
ı			Value is one of the following
ı			Manufacturer report = Manufacturer report
I			Voluntary report = Voluntary report
I			User facility report = User facility report
			Distributor report = Distributor report
Source	health_professional	string	Whether the initial reporter was a health professional (e.g. physician, pharmacist, nurse, etc.) or not.
I			
I			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
I			I
I			Value is one of the following
I			Y = The initial reporter is a health professional.
			N = The initial reporter is not a health professional.

Source			
	reporter_occupation_code	string	Initial reporter occupation.
			This is an exact field. It has been indexed both as its exact string content, and also believe in a
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			Physician = Physician
			Nurse = Nurse
			Health professional = Health professional
			Lay user/patient = Lay user/patient Other health care professional = Other health care professional
			Other health care professional = Other health care professional Audiologist = Audiologist
			Audiologist = Audiologist Dental hygienist = Dental hygienist
			Detician ingene Dietician pgenis. Dietician el Detician pgenis.
			Emergency medical technician = Emergency medical technician
			Medical technologist = Medical technologist
			Nuclear medicine technologist = Nuclear medicine technologist
			Occupational therapist = Occupational therapist Paramedic = Paramedic
			Paramedic = Paramedic Pharmacist = Pharmacist
			Phiebotomist = Phiebotomist
			Physical therapist = Physical therapist
			Physician assistant = Physician assistant
			Radiologic technologist = Radiologic technologist
			Respiratory therapist = Respiratory therapist Speech therapist = Speech therapist
			Speech therapist = Speech therapist Dentist = Dentist
Source	initial_report_to_fda	string	Whether the initial reporter also notified or submitted a copy of this report to FDA.
			The state of the s
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			Yes = FDA was also notified by the initial reporter.
			No = FDA was not notified by the initial reporter. Unknown = Unknown whether FDA was also notified by the initial reporter.
			No answer provided or empty = This information was not provided.
Source	reprocessed_and_reused_flag	string	Indicates whether the suspect device was a single-use device that was reprocessed and reused on a patient.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			Y = Was a single-use device that was reprocessed and reused.
			N = Was not a single-use device that was reprocessed and reused. UNK = The original equipment manufacturer was unable to determine if their single-use device was reprocessed and reused.
Device	device.device_sequence_number	string	Number identifying this particular device. For example, the first device object will have the value 1. This is an enumeration corresponding to the number of patients
l			involved in an adverse event.
		1	This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Device	device_device_event_key	string	Documentation forthcoming.
Device Identification	device.date_received device.brand_name	string string	Documentation forthcoming The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog (e.g. Flo-Easy Catheter, Reliable Heart Pacemaker, etc.). If the
racidilication	de vice. or and_name	act mig	suspect device is a reprocessed single-use device, this field will contain NA.
		1	This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Identification	device.generic_name	string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.).
Identification	device.generic_name	string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.).
			The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an exact field. It has been indexed both as its exact string content, and also tokenized.
Identification Identification Identification	device.generic_name device.udi. di device.udi. public	string string string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.).
Identification	device.udi_di	string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UDI-D1 and the parts of the Production identifier (PI) that would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 1) lot or batch number within which a device was
Identification	device.udi_di	string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model: Includes both the UD-D and the parts of the Production identifier (P) has twood not identify an individual patient. The Production Identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 3) to 4 schick make the analysis of the production of
Identification Identification	device.udi_di device.udi_public	string string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-ID and the parts of the Production identifier (PI) hat would not identify an individual patient. The Production Identifier (PI) arise to product on identifier (PI) hat would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 1) lot or batch number within which a device was manufactured, 2) serial number of a specific device, 2) expiration date of a specific device, 4) date a specific device was manufactured, and 5) distinct identification code required by \$127.12.09(c) for a human cell, tissue, or cellular and tissue-based product [167.79] regulated as a device.
Identification	device.udi_di	string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model: Includes both the UD-D and the parts of the Production identifier (P) has twood not identify an individual patient. The Production Identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 3) to 4 schick make the analysis of the production of
Identification Identification	device.udi_di device.udi_public	string string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-ID and the parts of the Production identifier (P) hat would not identify an individual patient. The Production Identifier (P) har includes both the UD-ID and the parts of the Production identifier (P) hat would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 1) to or batch number within which a device was namufactured, as specific device, a specific device, 4) are specified (evice was manufactured, and 5) distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. Three-letter FDA Product Classification Code. Medical devices are classified under 21 CFR Parts 862-892.
Identification Identification	device.udi_di device.udi_public	string string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-ID and the parts of the Production identifier (PI) hat would not identify an individual patient. The Production Identifier (PI) arise to product on identifier (PI) hat would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 1) lot or batch number within which a device was manufactured, 2) serial number of a specific device, 2) expiration date of a specific device, 4) date a specific device was manufactured, and 5) distinct identification code required by \$127.12.09(c) for a human cell, tissue, or cellular and tissue-based product [167.79] regulated as a device.
Identification Identification	device.udi_di device.udi_public	string string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-ID and the parts of the Production identifier (P) hat would not identify an individual patient. The Production Identifier (P) har includes both the UD-ID and the parts of the Production identifier (P) hat would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 1) to or batch number within which a device was namufactured, a pacific device, a specified device, 4) are specified (evice was manufactured, and 5) distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. Three-letter FDA Product Classification Code. Medical devices are classified under 21 CFR Parts 862-892.
Identification Identification	device.udi_di device.udi_public	string string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-10 and the parts of the Production identifier (P) lat would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 1) to or batch number within which a device was manufactured, part of the production of a specific device, 2) justifiant other of a specific device, 2) departs on the control of the production of
Identification Identification	device.udi_di device.udi_public device.device_report_product_code	string string string	This is an exact field. It has been indexed both as its exact string content, and also tokenized. This is an exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UDi-DI and the parts of the Production identifier (PI) that would not identify an individual patient. The Production identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 3) lot or batch number within which a device was manufactured, 2) serial number of a specific device, 3) expiration date of a specific device, 4) date a specific device was manufactured, and 5) distinct identification code required by §1271.250(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. For e more information, see Product Classification Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) The exact model number found on the device label or accompanying packaging.
Identification Identification Identification	device.udi_di device.udi_public device.device_report_product_code device.model_number	string string string string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific toa device version or model. Includes both the UD-D1 and the parts of the Production identifier (P) has two would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UD that identifies one or more of the following when included on the label of a device and may include: 1) to or batch number within which a device was manufactured, paseful device, 3) experistion date of a specific device, 3) experistion date of a specific device was manufactured, and 5) distinct identification code required by §1271.390(j for a human cell, tissue, or cellular and tissue-based product (ICT/P) regulated as a device. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. For emore information, see Product Classification Database (http://www.accessdata.fda gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) The exact model number found on the device label or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Identification Identification	device.udi_di device.udi_public device.device_report_product_code	string string string	This is an exact field. It has been indexed both as its exact string content, and also tokenized. This is an exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UDi-DI and the parts of the Production identifier (PI) that would not identify an individual patient. The Production identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 3) lot or batch number within which a device was manufactured, 2) serial number of a specific device, 3) expiration date of a specific device, 4) date a specific device was manufactured, and 5) distinct identification code required by §1271.250(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. For e more information, see Product Classification Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) The exact model number found on the device label or accompanying packaging.
Identification Identification Identification	device.udi_di device.udi_public device.device_report_product_code device.model_number	string string string string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-D and the parts of the Production identifier (P) that would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UD that identifies one or more of the following when included on the label of a device and may include: 3) to to batch number within which a device was manufactured, parts of the production identifier on a specific device, 3) experiation date of a specific device was manufactured, and 5) distinct identification code required by §1271.290(c) for a human cell, itsue, or cellular and tissue-based product (IE(T/P) regulated as a device. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. For emore information, see Product Classification Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) The exact model number found on the device label or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. The exact model number found on the device label or accompanying packaging.
Identification Identification Identification Identification Identification	device.udi_public device.udi_public device.device_report_product_code device.device_number device_catalog_number	string string string string string string	This is an exact field. It has been indexed both as its exact string content, and also tokenized. This is an exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UDi-DI and the parts of the Production identifier (PI) that would not identify an individual patient. The Production identifier is a conditional, variable protion of a UDI bit hat identifies one or more of the following when included on the label of a device and any include: 1) to or batch number within which a device was manufactured, 2) serial number of a specific device, 3) expiration date of a specific device, 4) date a specific device was manufactured, and 5) distinct identification code required by §1272.1290(c) for a human cell, tissue, or ceitlular and tissue-based product (HCT/P) regulated as a device. This is an exact field. It has been indexed both as its exact string content, and also tokenized. For e more information, see Product Classification Database (http://www.accessdata.fda.gov/scripts/cdriv/cdriocs/c/PCD/classification.cfm) The exact model number found on the device label or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. The exact model number found on the device label or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Identification Identification Identification	device.udi_di device.udi_public device.device_report_product_code device.model_number	string string string string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-D and the parts of the Production identifier (P) that would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UD that identifies one or more of the following when included on the label of a device and may include: 3) to to batch number within which a device was manufactured, parts of the production identifier on a specific device, 3) experiation date of a specific device was manufactured, and 5) distinct identification code required by §1271.290(c) for a human cell, itsue, or cellular and tissue-based product (IE(T/P) regulated as a device. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. For emore information, see Product Classification Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) The exact model number found on the device label or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. The exact model number found on the device label or accompanying packaging.
Identification Identification Identification Identification Identification Identification	device.udi_public device.udi_public device.device_report_product_code device.device_number device_catalog_number	string string string string string string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-D1 and the parts of the Production identifier (Pl) that would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UD1 that identifies one or more of the following when included on the label of a device and may include: 1) to to batch number within which a device was manufactured, and 5) distinct identification of a UD1 that identifies one or more of the following when included on the label of a device and may include: 1) to to batch number within which a device was manufactured, and 5) distinct identification code required by \$1271.290(c) for a human cell, tissue, or cellular and tissue-based product (IE(TP) regulated as a device. Three-letter Fo Product Classification Ode. Medical devices are classified under 21 CER PARS 862-892. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. For emore information, see Product Classification Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) The exact model number found on the device label or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. If wailable, the lot number found on the label or packaging material. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
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Identification Identification Identification Identification Identification Identification	device.udi_di device.udi_public device.device_report_product_code device.model_number device_catalog_number device_lot_number	string string string string string string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-D1 and the parts of the Production identifier (Pl) that would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UD1 that identifies one or more of the following when included on the label of a device and may include: 1) to to batch number within which a device was manufactured, and 5) distinct identification of a UD1 that identifies one or more of the following when included on the label of a device and may include: 1) to to batch number within which a device was manufactured, and 5) distinct identification code required by \$1271.290(c) for a human cell, tissue, or cellular and tissue-based product (IE(TP) regulated as a device. Three-letter Fo Product Classification Ode. Medical devices are classified under 21 CER PARS 862-892. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. For emore information, see Product Classification Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) The exact model number found on the device label or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. If wailable, the lot number found on the label or packaging material. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
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identification	device.udi_di device.udi_public device.udi_public device.device_report_product_code device.model_number device_catalog_number device.other_id_number device.other_id_number device.other_id_number device.device.age_text device.device_ayailability	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-10 and the parts of the Production identifier (PI) that would not identify an individual patient. The Production identifier is a conditional, variable protion of a UDI but alreading on or more of the following when included on the label of a device as an authority of the but has intentified on or more of the following when included on the label of a device as an authority of the lath number of a specific device, 3) expiration date of a specific device, 4) date a specific device was manufactured, 2) serial number of a specific device, 8) expiration date of a specific device, 4) date a specific device was manufactured, and 5) distinct identification code required by \$1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. For emore information, see Product Classification Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) The exact model number found on the device label or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. The exact model number found on the label or packaging material. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. If available, the lot number found on the label or packaging material. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. If available, the lot number found on the labele or packaging material. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. If available, the lot number found on the labele or packaging material. This is an .exact field. It has been indexed both as its exact strin
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identification	device.udi_di device.udi_public device.udi_public device.device_report_product_code device.model_number device_catalog_number device.other_id_number device.other_id_number device.other_id_number device.device.age_text device.device_ayailability	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. A unique numeric or alphanumeric code specific to a device version or model. Includes both the UD-10 and the parts of the Production identifier (PI) that would not identify an individual patient. The Production identifier is a conditional, variable protion of a UDI but alreading on or more of the following when included on the label of a device as an authority of the but has intentified on or more of the following when included on the label of a device as an authority of the lath number of a specific device, 3) expiration date of a specific device, 4) date a specific device was manufactured, 2) serial number of a specific device, 8) expiration date of a specific device, 4) date a specific device was manufactured, and 5) distinct identification code required by \$1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. For emore information, see Product Classification Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) The exact model number found on the device label or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. The exact model number found on the label or packaging material. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. If available, the lot number found on the label or packaging material. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. If available, the lot number found on the labele or packaging material. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. If available, the lot number found on the labele or packaging material. This is an .exact field. It has been indexed both as its exact strin

Use of Device	device.device_operator	string	The person using the medical device at the time of the adverse event. This may be a health professional, a lay person, or may not be applicable.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Make it and a falls falls with
			Value is one of the following Physician = Physician
			Nurse = Nurse Health professional = Health professional
			Lay user/patient = Lay user/patient
			Other health care professional = Other health care professional Audiologist = Audiologist
			Dental hygienist = Dental hygienist
			Dietician = Dietician Emergency medical technician = Emergency medical technician
			Medical technologist = Medical technologist Nuclear medicine technologist = Nuclear medicine technologist
			Occupational therapist = Occupational therapist
			Paramedic = Paramedic Pharmacist = Pharmacist
			Phlebotomist = Phlebotomist
			Physical therapist = Physical therapist Physician assistant = Physician assistant
			Radiologic technologist = Radiologic technologist Respiratory therapist = Respiratory therapist
			Speech therapist = Speech therapist
Use of Device	device.implant_flag	string	Dentist = Dentist Whether a device was implanted or not. May be either marked N or left empty if this was not applicable.
ose of Device	device.impairc_nag	string	
Use of Device	device.date_removed_flag	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Whether an implanted device was removed from the patient, and if so, what kind of date was provided.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			Month and year provided only day defaults to 01 = Only a year and month were provided. Day was set to 01. Year provided only = Only a year was provided. Month was set to 01 (January) and day set to 01.
			No information at this time = Documentation forthcoming. Not available = Documentation forthcoming.
		1	Unknown = Documentation forthcoming.
		1	* = Documentation forthcoming. B = Documentation forthcoming.
Manufactures	de ées manufactures d'année	atain a	V = Documentation forthcoming.
Manufacturer	device.manufacturer_d_name	string	Device manufacturer name.
Manufacturer	device manufacturer d address 1	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Device manufacturer address line 1.
	device.manufacturer_d_address_1	string	
Manufacturer	device.manufacturer d address 2	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Device manufacturer address line 2.
]			
Manufacturer	device.manufacturer_d_city	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Device manufacturer city.
Manufacturer	device.manufacturer_d_state	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Device manufacturer state code
			This is an award field it has been independ both as its event design content and also below inside
Manufacturer	device.manufacturer_d_zip_code	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Device manufacturer zip code.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_zip_code_ext	string	Device manufacturer zip code extension.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_postal_code	string	Device manufacturer postal code.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_country	string	Device manufacturer country.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Patient Patient	patient.date_received patient.patient_sequence_number	string string	Date the report about this patient was received. Documentation forthcoming.
Patient	patient.patient_problems	array of strings	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Describes actual adverse effects on the patient that may be related to the device problem observed during the reported event.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Patient	patient.sequence_number_outcome	array of strings	Outcome associated with the adverse event for this patient. Expect wide variability in this field; each string in the list of strings may contain multiple outcomes,
		1	separated by commas, and with numbers, which may or may not be related to the patient_sequence_number.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			Life Threatening = Life Threatening
			Hospitalization = Hospitalization Disability = Disability
			Congenital Anomaly = Congenital Anomaly Required Intervention = Required Intervention
			Other = Other
			Invalid Data = Invalid Data Unknown = Unknown
		1	No Information = No Information
			Not Applicable = Not Applicable Death = Death
Patient	patient.sequence_number_treatment	array of strings	
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Report text Report text	mdr_text.date_report mdr_text.mdr_text_key	string string	Date the initial reporter (whoever initially provided information to the user facility, manufacturer, or importer) provided the information about the event. Documentation forthcoming.
neport text	_centuriti_tent_ney	Still B	
Report text	mdr text.patient sequence number	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Number identifying this particular patient. For example, the first patient object will have the value 1. This is an enumeration corresponding to the number of patients
.,			involved in an adverse event.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Report text	mdr_text.text	string	Narrative text or problem description.
Ī			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	mdr_text.text_type_code	string	String that describes the type of narrative contained within the text field.
Report text			1
Report text			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Report text			
Report text			Value is one of the following Description of Event or Problem = The problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or
Report text			Value is one of the following Description of Event or Problem = The problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. For patient adverse events, may include a description of the event in detail using the reporter's own words,
Report text			Value is one of the following Description of Event or Problem = The problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or maifunction of the medical product can be understood. For patient adverse events, may include a description of the event in detail using the reporter's own words, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, may include synopses of any office visit notes or the hospital
Report text			Value is one of the following Description of Event or Problem = The problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. For patient adverse events, may include a description of the event in detail using the reporter's own words, including a description of what happened and a summary of all relevant inclinal information (medical status prior to the event; signs and/or symptoms, differential
Report text			Value is one of the following Description of Event or Problem = The problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. For patient adverse events, may include a description of the event in detail using the reporter's own words, including a description of what happened and a summary of all relevant inclinal information in medical status prior to the event; sign of symptoms; differential diagnosis for the event in question; clinical course; treatment, outcome, etc.). If available and if relevant, may include synopses of any office visit notes or the hospital disdarges summary. This section may also contain information about surgical procedures and laboratory tests.

By user facility/importer			
by user racinty/importer	type_of_report	string	The type of report.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
I	Ì		
			Value is one of the following
			Initial submission = Initial report of an event. Followup = Additional or corrected information.
I	Ì		Extra copy received = Documentation forthcoming.
	The same		Other information submitted = Documentation forthcoming.
By user facility/importer	date_facility_aware	string	Date the user facility's medical personnel or the importer (distributor) became aware that the device has or may have caused or contributed to the reported event.
By user facility/importer	report_date	string	Date of the report, or the date that the report was forwarded to the manufacturer and/or the FDA.
By user facility/importer	report_to_fda	string	Whether the report was sent to the FDA by a user facility or importer (distributor). User facilities are required to send reports of device-related deaths. Importers are
			required to send reports of device-related deaths and serious injuries.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			Y = The report was sent to the FDA by a user facility or importer.
			N = The report was not sent to the FDA by a user facility or importer.
By user facility/importer By user facility/importer	date_report_to_fda report_to_manufacturer	string string	Date the user facility/importer (distributor) sent the report to the FDA, if applicable. Whether the report was sent to the manufacturer by a user facility or importer (distributor). User facilities are required to send reports of device-related deaths and
			serious injuries to manufacturers. Importers are required to send reports to manufacturers of device-related deaths, device-related serious injuries, and device-related
			malfunctions that could cause or contribute to a death or serious injury.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following Y = The report was sent to the manufacturer by a user facility or importer.
			N = The report was not sent to the manufacturer by a user facility or importer.
By user facility/importer	date_report_to_manufacturer event location	string string	Date the user facility/importer (distributor) sent the report to the manufacturer, if applicable. Where the event occurred.
By user facility/importer	event_location	String	where the event occurred.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
Ī	Ì		Other = Other
			Hospital = Hospital
Ī	Ì		Home = Home Nursing home = Nursing home
]			Outpatient treatment facility = Outpatient treatment facility
]			Outpatient diagnostic facility = Outpatient diagnostic facility Ambulatory surgical facility = Ambulatory surgical facility
]			Ambulatory surgical facility = Ambulatory surgical facility Catheterization suite = Catheterization suite
			Critical care unit = Critical care unit
			Dialysis unit = Dialysis unit Emergency room = Emergency room
			Examination room = Examination room
			Laboratory/pathology department = Laboratory/pathology department
			Maternity ward - nursery = Maternity ward - nursery Operating room = Operating room
			Outpatient clinic/surgery = Outpatient clinic/surgery
			Patients room or ward = Patients room or ward
			Radiology department = Radiology department Ambulatory health care facility = Ambulatory health care facility
			Ambulatory surgical center = Ambulatory surgical center
Name and address	distributor_name	string	Blood bank = Blood bank User facility or importer (distributor) name.
ivalile aliu audiess	distributor_name	string	Oser launcy or importer (distributor) name.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address	distributor_address_1	string	User facility or importer (distributor) address line 1.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address	distributor_address_2	string	User facility or importer (distributor) address line 2.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address	distributor_city	string	User facility or importer (distributor) city.
1			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
		string	
Name and address	distributor_state	Sti iiig	User facility or importer (distributor) two-digit state code.
	distributor_state	string	
	distributor_state distributor_zip_code	string	User Tacility or importer (instributor) two-bigst state code. This is an exeact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 5-digit zip code.
Name and address			This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 5-digit zip code.
Name and address			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address Name and address	distributor_zip_code	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 5-digit zip code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 4-digit zip code extension (zip+4 code).
Name and address Name and address Name and address	distributor_zip_code distributor_zip_code_ext	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 5-digit zip code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 4-digit zip code extension (zip+4 code). This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address Name and address	distributor_zip_code	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 5-digit zip code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 4-digit zip code extension (zip+4 code). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Suspect medical device manufacturer name.
Name and address Name and address Name and address Suspect device manufacturer	distributor_zip_code distributor_zip_code_ext manufacturer_name	string string string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 5-digit zip code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 4-digit zip code extension (zip+4 code). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Suspect medical device manufacturer name. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address Name and address Name and address	distributor_zip_code distributor_zip_code_ext	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 5-digit zip code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. User facility or importer (distributor) 4-digit zip code extension (zip+4 code). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Suspect medical device manufacturer name.
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OpenFDA fields	regulation_number	array of strings	The classification regulation in the Code of Federal Regulations (CFR) under which the device is identified, described, and formally classified (Code of Federal
			regulations Title 21, 862.00 through 892.00). The classification regulation covers various aspects of design, clinical evaluation, manufacturing, packaging, labeling, and
			postmarket surveillance of the specific medical device.