Section	Field Name	Туре	Description
	brand_name	string	The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand
Ì		1	name is the name that is typically registered with USPTO and have the * and/or TM symbol.
			The state of the s
	catalog_number	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized. The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.
	Catalog_named	30.1116	The catalog, reserved, or product number round on the device label of accompanying packaging to definity a particular product.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	commercial_distribution_end_date	date	Indicates the date the device is no longer held or offered for sale. See 21 CFR 807.3(b) for exceptions. The device may or may not still be available for purchase in the marketplace.
	commercial_distribution_status	string	Indicates whether the device is in commercial distribution as defined under 21 CFR 807.3(b).
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			In Commercial Distribution = In Commercial Distribution
	company_name	string	Not in Commercial Distribution = Not in Commercial Distribution Company name associated with the labeler DUNS Number entered in the DI Record.
	de Service Se have reduce		This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	device_count_in_base_package device description	integer	Number of medical devices in the base package. Additional relevant information about the device that is not already captured as a distinct GUDID data attribute.
	has_donation_id_number	boolean	The Donation Identification Number is applicable to devices that are also regulated as HCT/Ps and is a number that is assigned to each
			donation. This number/code is required to be part of the UDI when included on the label in order to provide the means to track the device back to
			its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labeling, distribution and use to be determined.
			Value is one of the following
			true = true false = false
			Talse = Talse
	has_expiration_date	boolean	The date by which the label of a device states the device must or should be used. This date is required to be part of the UDI when included on the
			label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device
			manufacturing, packaging, labeling, distribution and use to be determined.
			Value is one of the following
			true = true
	has_lot_or_batch_number	boolean	false = false The number assigned to one or more device(s) that consist of a single type, model, class, size, composition, or software version that are
		_ concult	manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits. This
		1	number is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing
			source or otherwise allow the history of the device manufacturing, packaging, labeling, distribution and use to be determined.
			Value is one of the following
			true = true
			false = false
	has_manufacturing_date	boolean	The date on which a device is manufactured. This date is required to be part of the UDI when included on the label in order to provide the means
			to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labeling, distribution
			and use to be determined.
			Value is one of the following
			true = true
	La contra de la contra del la contra del la contra del la contra del la contra de la contra del la contra	besteen	false = false The number that allows for the identification of a device, indicating its position within a series. This number is required to be part of the UDI when
	has_serial_number	boolean	included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the
			device manufacturing, packaging, labeling, distribution and use to be determined.
			Value is one of the following
			true = true
			true = true false = false
	is_combination_product	boolean	false = false Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and
	is_combination_product	boolean	false = false Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity, packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR
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	is_combination_product	boolean	false a false Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity, packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case. Value is one of the following
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	is_combination_product is_direct_marking_exempt	boolean	false a false Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case. Value is one of the following
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	is_direct_marking_exempt is_hct_p is_kkt is_labeled_as_no_nrl is_labeled_as_nrl	boolean boolean boolean boolean	false a false Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity, packaged together as a single package, or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case. Value is one of the following true a true false exempt from Direct Marking requirements under 21 CFR 801.45. Value is one of the following true a true false false false indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3. Value is one of the following true a true false shall be sh
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	is_direct_marking_exempt is_hct_p is_hct_p is_labeled_as_no_nri is_labeled_as_nri is_labeled_as_nri is_otc is_pm_exempt is_rx	boolean boolean boolean boolean boolean boolean	false = false Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity, packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the following true = true false = false The device is exempt from Direct Marking requirements under 21 CFR 801.45. Value is one of the following true = true indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3. Value is one of the following true = true into a human recipient as defined under 21 CFR 1271.3. Value is one of the following true = true into a human recipient as defined under 21 CFR 1271.3. Value is one of the following true = true into a human recipient as defined under 21 CFR 1271.3. Value is one of the following true = true false = false Indicates that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and are being distributed as a medical device. Value is one of the following true = true false = false Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container and the device labeling contains this information. Only applicable to devices not subject to the requirements under 21 CFR 801.437. Not all medical products that are NOT made with natural rubber latex was not used as materials in the manufacture of the medical product and container and the device labeling contains this information. Only applicable to devices not subject to the requirements under 21 CFR 801.437. The value true indicates that the device label or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437.
	is_direct_marking_exempt is_hct_p is_hct_p is_labeled_as_no_nri is_labeled_as_nri is_labeled_as_nri is_otc is_pm_exempt is_rx	boolean boolean boolean boolean boolean boolean	false of false Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package, or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the following true = true false = false The device is exempt from Direct Marking requirements under 21 CFR 801.45. Value is one of the following true = true false = false The device is exempt from Direct Marking requirements under 21 CFR 801.45. Value is one of the following true = true false = false Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3. Value is one of the following true = true false = false Indicates that the device is a convenience, combination, in vitro diagnostic (IVO), or medical procedure kit. Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and are being distributed as a medical device. Value is one of the following true = true false = false Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container and the device labeling contains this information. Only applicable to devices not subject to the requirements under 21 CFR 801.437. Not all medical products that are NOT made with natural rubber latex was not used as materials in the manufacture of the medical product and container and the device labeling contains this information. Only applicable to devices not subject to the requirements under 21 CFR 801.437. Not all medical products that are NOT made with natural rubber latex with the manufacture of the medical product and container and the device labeling contains natural rubber that contacts humans as described under 21 CFR 801.437. The value true indicates that the device or packaging c
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	is_direct_marking_exempt is_hct_p is_hct_p is_labeled_as_no_nri is_labeled_as_nri is_labeled_as_nri is_otc is_pm_exempt is_rx	boolean boolean boolean boolean boolean boolean	false of false Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package, or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the following true = true false = false The device is exempt from Direct Marking requirements under 21 CFR 801.45. Value is one of the following true = true false = false The device is exempt from Direct Marking requirements under 21 CFR 801.45. Value is one of the following true = true false = false Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3. Value is one of the following true = true false = false Indicates that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and are being distributed as a medical device. Value is one of the following true = true false = false Indicates that natural rubber lates was not used as materials in the manufacture of the medical product and container and the device labeling contains this information. Only applicable to devices not subject to the requirements under 21 CFR 801.437. Not all medical products that are NOT made with natural rubber lates was not used as materials in the manufacture of the medical product and container and the device labeling contains this information. Only applicable to devices not subject to the requirements under 21 CFR 801.437. Not all medical products that are NOT made with natural rubber lates with be marked. Value is one of the following true = true false = false Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. The value true indicates

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I	mri_safety	string	Indicates the MRI Safety Information, if any, that is present in the device labeling. Please see the ASTM F2503-13 standard for more information.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
			Value is one of the following
			MR Safe = MR Safe MR Unsafe = MR Unsafe
			MR Conditional = MR Conditional
			Labeling does not contain MRI Safety Information = Labeling does not contain MRI Safety Information
	public_version_date	date	Auto assigned the day file is generated with Time Stamp; All existing records will have first date assigned the day download file is generated with
			this data element.
	public_version_number	string	Auto assigned version number, assigned just before file generation; All existing records will have version 1 assigned.
	public version status	string	Definition forthcoming.
	publish_date	date	Indicates the date the DI Record gets published and is available via Public Search.
	record_key	string	Current enhancements will allow the Primary DI to change after the DI record has been released to the public. To ensure records can be linked and
			managed, a record key will be provided; Unique alphanumeric value, auto generated.
	record_status	string	Indicates the status of the DI Record.
			Value is one of the following
			Published = Published Unpublished = Unpublished
			Deactivated = Deactivated
	sterilization.is_sterile	boolean	Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.
			Value is one of the following
			true = true false = false
	sterilization.is_sterilization_prior_use	boolean	Indicates that the device requires sterilization prior to use.
			Value is one of the following
			true = true
 	sterilization.sterilization_methods	string	false = false Indicates the method(s) of sterilization that can be used for this device.
	_	ا	
			Value is one of the following Chlorine Dioxide = Chlorine Dioxide
			Dry Heat Sterilization = Dry Heat Sterilization
			Ethylene Oxide = Ethylene Oxide High Intensity Light or Pulse Light = High Intensity Light or Pulse Light
			High-level Disinfectant = High-level Disinfectant
			Hydrogen Peroxide = Hydrogen Peroxide Liquid Chemical = Liquid Chemical
			Microwave Radiation = Microwave Radiation
			Moist Heat or Steam Sterilization = Moist Heat or Steam Sterilization Nitrogen Dioxide = Nitrogen Dioxide
			Ozone = Ozone
			Peracetic Acid = Peracetic Acid Radiation Sterilization = Radiation Sterilization
			Sound Waves = Sound Waves
			Supercritical Carbon Dioxide = Supercritical Carbon Dioxide Ultraviolet Light = Ultraviolet Light
	product_codes.code	string	A three-letter identifier assigned to a device category
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	product_codes.name	string	Name associated with the three-letter Product Code
	version_or_model_number	string	The version or model found on the device label or accompanying packaging used to identify a category or design of a device. The version or model
			identifies all devices that have specifications, performance, size, and composition within limits set by the labeler.
Device identifiers	identifiers.id	string	This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Device identifiers Device identifiers	identifiers.id identifiers.issuing_agency	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 to a device version or model. Identifies whether facility is an initial importer.
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Storage and Handling	storage.special_conditions	string	First line of address for owner operator.
Storage and Handling	storage.type	string	Second line of address for owner operator.
OpenFDA fields	device_class	string	A risk based classification system for all medical devices ((Federal Food, Drug, and Cosmetic Act, section 513)
			Value is one of the following
			1 = Class I (low to moderate risk): general controls
			2 = Class II (moderate to high risk): general controls and special controls
			3 = Class III (high risk): general controls and Premarket Approval (PMA)
			U = Unclassified
			N = Not classified
			F = HDE
OpenFDA fields	device name	string	This is the proprietary name, or trade name, of the cleared device.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
OpenFDA fields	fei number		Facility identifier assigned to facility by the FDA Office of Regulatory Affairs.
OpenFDA fields	medical specialty description		Regulation Medical Specialty is assigned based on the regulation (e.g. 21 CFR Part 888 is Orthopedic Devices) which is why Class 3 devices lack the
		" "	"Regulation Medical Specialty" field.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
OpenFDA fields	regulation number		The classification regulation in the Code of Federal Regulations (CFR) under which the device is identified, described, and formally classified (Code
	1-8		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.