Section	Field Name	Type	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 name is the name that is typically registered with USPTO and have the ® and/or TM symbol. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	catalog_number	string	The catalog, reference, or product number found on the device label or accompanying packaging to identify 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 Not in Commercial Distribution = Not in Commercial Distribution

	company_name	string	Company name associated with the labeler DUNS Number entered in the DI Record. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Customer Contacts	customer_contacts.email	string	Email for the customer contact; to be used by patients and consumers for device-related questions.
Customer Contacts	customer_contacts.phone	string	Phone number for the customer contact; to be ued by patients and consumers for device-related questions.
	device_count_in_base_package	integer	Number of medical devices in the base package.
	device_description	string	Additional relevant information about the device that is not already captured as a distinct GUDID data attribute.
Device Size	device_sizes.text	string	Additional undefined device size not represented in the GUDID Size Type LOV.

Device Size	device_sizes.type	string	Dimension type for the clinically relevant measurement of the medical device. Value is one of the following Circumference = Circumference Depth; Device Size Text, specify = Depth; Device Size Text, specify Catheter Gauge= Catheter Gauge Outer Diameter: Outer Diameter Height = Height Length = Length Lumen/Inner Diameter = Lumen/Inner Diameter Needle Gauge = Needle Gauge Total Volume = Total Volume Width = Width Weight = Weight Pressure = Pressure Pore Size = Pore Size Area/Surface Area = Area/Surface Area Angle = Angle

Device Size	device_sizes.unit	string	The unit of measure associated with each clinically relevant size. Value is one of the following Centiliter = Centiliter Centimeter = Centimeter Cubic Inch = Cubic Inch Cup = Cup Deciliter = Deciliter Decimeter = Decimeter degree = degree Feet = Feet Femtoliter = Femtoliter Femtometer = Femtometer Fluid Ounce = Fluid Ounce French = French Gallon = Gallon Gauge = Gauge Gram = Gram Hertz = Hertz Inch = Inch Kilogram = Kilogram Kiloliter = Kiloliter Kilometer = Kilometer KiloPascal = KiloPascal Liter = Liter Meter = Meter
Device Size	device_sizes.value	string	Numeric value for the clinically reevant size measurement of the medical device.
GMDN terms	gmdn_terms.code	string	GMDN preferred term Code of the common device type associated with the FDA PT Code.
GMDN terms	gmdn_terms.definition	string	Definition of the common device type associated with the GMDN Preferred Term Code/FDA PT Code

GMDN terms	gmdn_terms.name	string	Name of the common device type associated with the GMDN Preferred Term Code/ FDA PT Code.. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
GMDN terms	gmdn_terms.implantable	boolean	GMDN Implantable flag Value of one of the following: true = true false = false
GMDN terms	gmdn_terms.code_status	boolean	GMDN Term Status, Active or Obsolete Value of one of the following: Active = Active Obsolete = Obsolete
	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

	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 false = false
	has_lot_or_batch_number	boolean	The number assigned to one or more device(s) that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits. This 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 false = false
	has_serial_number	boolean	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 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
Device Identifiers	identifiers.id	string	A unique numeric or alphanumeric cide specific to a device version or model.

Device Identifiers	identifiers.issuing_agency	string	Organization accredited by FDA to operate a system for the issuance of UDIs. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following GS1 = GS1 ICCBBA = ICCBBA HIBCC = HIBCC NDC/NHRIC = NDC/NHRIC
Device Identifiers	identifiers.package_discontinue_date	date	Indicates the date this particular package configuration is diiscontinued by the Labeler or removed from the marketpace.
Device Identifiers	identifiers.package_status	string	Indicates whether the package 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 Not in Commercial Distribution = Not in Commercial Distribution
Device Identifiers	identifiers.packakage_type	string	The type of packaging used for the device.
Device Identifiers	identifiers.quantity_per_package	integer	The number of package with the same Primary DI or Package DI within a given packaging configuration.

Device Identifiers	identifiers.type	string	Indicates whether the identifier is the Primary, Secondary, Direct Marking, Unit of Use, Package, or Previous DI. Value is one of the following Primary = Primary DI. An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest package level of a medical device containing a full UDI. For medical devices without packaging, the primary DI number and full UDI may be on the device itself." Secondary = Secondary DI. An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI. Under 21 CFR 830.40(a), only one device identifier from any particular system for the issuance of UDIs may be used to identify a particular version or model of a device. Direct Marking = Direct Marking DI. An identifier that is marked directly on the medical device and is different than the Primary DI Number; only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45. Unit of Use = Unit of Use DI. An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient

Device Identifiers	identifiers_unit_od use_id	string	An identifier assigned to an individual medicaldevice when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient. Unit of Use DI is an identifier used by hospital staff and Material amangemnet to account for a single device when the UDI is labeled on a higher level of packaging. The Unit of Use DI does not appear on the label. Data type and field length are determined by the individual Issuing Agency structure.
	is_combination_product	boolean	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 = true false = false
	is_direct_marking_exempt	boolean	The device is exempt from Direct Marking requirements under 21 CFR 801.45. Value is one of the following true = true false = false

	is_hct_p	boolean	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
	is_kit	boolean	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
	is_labeled_as_no_nrl	boolean	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 will be marked. Value is one of the following true = true false = false

	is_labeled_as_nrl	boolean	Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. The value true indicates that the device label or packaging contains one of the following statements: (1) 'Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions', (2) 'This Product Contains Dry Natural Rubber', (3) 'Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions' or (4) 'The Packaging of This Product Contains Dry Natural Rubber'. Value is one of the following true = true false = false
	is_otc	boolean	Indicates that the device does not require a prescription to use and can be purchased over the counter. Value is one of the following true = true false = false
	is_pm_exempt	boolean	Indicates whether the device is exempt from premarket notification requirements. Value is one of the following true = true false = false
	is_rx	boolean	Indicates whether the device requires a prescription. Value is one of the following true = true false = false

	is_single_use	boolean	Indicates that the device is intended for one use or on a single patient during a single procedure. Value is one of the following true = true false = false
	labeler_duns_number	string	The DUNS Number is a unique nine-digit identifier for businesses. It is used to establish a D&B® business credit file, which is often referenced by lenders and potential business partners to help predict the reliability and/or financial stability of the company in question.
	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
Premarket Submissions	premarket_submissions.submission_number	string	Number associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA.

Premarket Submissions	premarket_submissions.supplement_number	string	Number assigned by FDA to a supplemental application for approval of a change in a medical device with an approved PMA.
Premarket Submissions	premarket_submission.submission_type	string	Number assigned by FDA to a supplemental application for approval of a change in a medical device with an approved PMA. Value is one of the following 510(k) = 510(k) PMA = PMA PDP = PDP HDE = HDE BLA = BLA NDA = NDA
Product Codes	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	product_codes.name	string	Name associated with the three-letter Product Code
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	medical_specialty_description	string	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	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.
	publish_date	date	Indicates the date the DI Record gets published and is available via Public Search.
	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.

	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	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	sterilization.is_sterilization_prior_use	boolean	Indicates that the device requires sterilization prior to use. Value is one of the following true = true false = false

Sterilization	sterilization.sterilization_methods	string	Indicates the method(s) of sterilization that can be used for this device. 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

Storage and Handling	storage.high.unit	string	The high value unit of measure associated with the storage and handling conditions. Value is one of the following Degrees Celsius = Degrees Celsius Degrees Fahrenheit = Degrees Fahrenheit Degrees Kelvin = Degrees Kelvin Kilo Pascal = Kilo Pascal Percent (%) Relative Humidity, Millibar = Percent (%) Relative Humidity,Millibar
Storage and Handling	storage.high.value	string	Indicates the high value for storage and handling requirements
Storage and Handling	storage.low.unit	string	The low value unit of measures associated with the storage and handling conditions.
Storage and Handling	storage.low.value	string	Indicates the low value for storage and handling requirements Value is one of the following Degrees Celsius = Degrees Celsius Degrees Fahrenheit = Degrees Fahrenheit Degrees Kelvin = Degrees Kelvin Kilo Pascal = Kilo Pascal Percent (%) Relative Humidity, Millibar = Percent (%) Relative Humidity,Millibar
Storage and Handling	storage.special_conditions	string	Indicated any special storage requirements for the device.

Storage and Handling	storage.type	string	Indicates storage and handling requirements for the device including temperature, humidity, and atmospheric pressure. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Handling Environment Atmospheric Pressure = Handling Environment Atmospheric Pressure Handling Environment Humidity = Handling Environment Humidity Handling Environment Temperature = Handling Environment Temperature Special Storage Conditions = Special Storage Conditions Storage Environment Atmospheric Pressure = Storage Environment Atmospheric Pressure Storage Environment Humidity = Storage Environment Humidity Storage Environment Temperature = Storage Environment Temperature
	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. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
OpenFDA fields	fei_number	array of strings	Facility identifier assigned to facility by the FDA Office of Regulatory Affairs.