Section	Field Name	Type	Description
	brand_name	string	Brand name 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 bears the ™ and/or ® symbol. This is an exact field. It has been indexed that is an 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 that is an 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 807.81(a)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 807.65(i). This is an exact field. It has been indexed that is an exact string content, and also tokenized. Values 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 valuable D-U-N-S Number entered on the D-U-N-S Record This is an exact field. It has been indexed that is an exact string content, and also tokenized.
	device_count_in_base_package	integer	Number of product devices in the base package
	device_description	string	Additional commercial information about the device that is not otherwise contained in a device GS1/HIBCC data, UDI/DI.
	has_donation_id_number	boolean	The Donation Identification Number is applicable to devices that are also registered 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. Values 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. Values 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. Values 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. Values 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. Values is one of the following: true = true false = false
	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. Values 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. Values 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. Values 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. Values is one of the following: true = true false = false
	is_labeled_as_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. Values is one of the following: true = true false = false
	is_labeled_as_no_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: Has 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". Values 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. Values is one of the following: true = true false = false
	is_pmn_exempt	boolean	Indicates whether the device is exempt from premarket notification requirements. Values is one of the following: true = true false = false
	is_rx	boolean	Indicates whether the device requires a prescription. Values 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. Values is one of the following: true = true false = false
	labeler_duns_number	string	The D-U-N-S 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 suppliers to evaluate a company's reliability and credit-worthiness. It is also used to establish a profile 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 that is an exact string content, and also tokenized. Values 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 These Dump. All existing records will have first date assigned the day download file is generated with this version. This is an exact field.
	public_version_number	string	Auto assigned version number. assigned not before file preversion. All existing records will have version 1 assigned. This is an exact field. It has been indexed that is an exact string content, and also tokenized.
	public_version_status	string	Processing status for the record This is an exact field. It has been indexed that is an exact string content, and also tokenized.
	publish_date	date	Indicates the date the DI Record was published and is available on Public Search.
	record_key	string	Service 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: Values 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. Values is one of the following: true = true false = false
	sterilization.is_sterilization_prior_use	boolean	Indicates that the device requires sterilization prior to use. Values is one of the following: true = true false = false
	sterilization.sterilization_methods	string	Indicates the method(s) of sterilization that can be used for this device. Values 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 clear-letter identifier assigned to a device category. This is an exact field. It has been indexed that is an exact string content, and also tokenized.
	product_codes.name	string	Product code name.
	version_or_model_number	string	The version or model based 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 that is an exact string content, and also tokenized.
Device identifiers	identifiers.id	string	Unique numeric or alfanumeric code, used for a device identifier as specified
Device identifiers	identifiers.issuing_agency	string	Identifies whether facility is an initial importer. Values is one of the following: Y = Yes N = No
Device identifiers	identifiers.package_discard_date	date	Date that an expired package is discarded. ISO8601 yyyy-mm-dd.
Device identifiers	identifiers.package_status	array	Facility or US agent address line 1
Device identifiers	identifiers.package_type	array	Facility or US agent address line 2
Device identifiers	identifiers.quantity_per_package	integer	Facility or US agent city
			This is an exact field. It has been indexed that is an exact string content, and also tokenized.
Device identifiers	identifiers.type	array	Facility or US agent or foreign state or province
Device identifiers	identifiers.unit_of_use_id	string	Number of devices 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 that is an exact string content, and also tokenized.
Customer Contact	customer_contacts.email	string	Facility or US agent Zip code
			This is an exact field. It has been indexed that is an exact string content, and also tokenized.
Customer Contact	customer_contacts.phone	string	Email associated with the facility or US agent
			This is an exact field. It has been indexed that is an exact string content, and also tokenized.
Device Size	device_sizes.text	string	Facility foreign postal code
			This is an exact field. It has been indexed that is an exact string content, and also tokenized.
Device Size	device_sizes.type	array	Device identifier associated with the GMDN PT Name of the device (Kansas Edition)
Device Size	device_sizes.unit	array	Product Code associated with the GMDN PT Name of the device (Kansas Edition)
GMDN Terms	gmdn_terms.code	array	Product Code Name associated with the GMDN PT Name of the device (Kansas Edition)
GMDN Terms	gmdn_terms.name	array	Product Code Name associated with the GMDN PT Name of the device (Kansas Edition)
GMDN Terms	gmdn_terms.definition	array	Definition of the common device type associated with the GMDN Preferred Term Code/PT Code
GMDN Terms	gmdn_terms.implantable	boolean	GMDN Implantable flag Values is one of the following: true = true false = false
GMDN Terms	gmdn_terms.code_status	boolean	GMDN Term Status, Active or Obsolete Values is one of the following: Active = Active Obsolete = Obsolete
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 associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types:
Premarket Submissions	premarket_submissions.submission_type	string	Indicates the premarket submission type. Value is one of the following 510(K) = 510(K) PMA = PMA PDP = PDP HDE = HDE BLA = BLA NDA = NDA
Storage and Handling	storage.high.value	string	The high value unit of measure associated with the storage and handling conditions. This is an exact field. It has been indexed that is an exact string content, and also tokenized.
Storage and Handling		string	Indicates the high value for storage and handling requirements. This is an exact field. It has been indexed that is an exact string content, and also tokenized.
Storage and Handling	storage.low.value	string	The low value unit of measure associated with the storage and handling conditions. This is an exact field. It has been indexed that is an exact string content, and also tokenized.
Storage and Handling	storage.low.unit	string	Indicates the low value for storage and handling requirements. Value is one of the following: Kelvin = Kelvin Degrees Fahrenheit = Degrees Fahrenheit Degrees Kelvin = Degrees Kelvin Kilo Pascal = Kilo Pascal Percent (%) Relative Humidity, Millibar = Percent (%) Relative Humidity, Millibar This is an exact field. It has been indexed that is an exact string content, and also tokenized
Storage and Handling	storage.special_conditions	array	Indicates any special storage requirements for the device.
Storage and Handling	storage.type	array	Indicates storage and handling requirements for the device including temperature, humidity, and atmospheric pressure.
OpenFDA fields	device_class	string	A risk based classification system for all medical devices (Federal Food, Drug, and Cosmetic Act, section 513) Values 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 = Exempt
OpenFDA fields	device name	string	The trade proprietary name, or trade name, of the cleared device. This is an exact field. It has been indexed that is an exact string content, and also tokenized.
OpenFDA fields	fei_number	array of strings	Facility Identifier assigned to a firm by the FDA's FURLS (Field Urgent Review Listing)
OpenFDA fields	medical_specialty_description	string	Regulation Medical Specialty is assigned based on the regulations (e.g. 21 CFR Part 888 is Orthopaedic Devices) which is why Class 3 devices lack the "Regulation Medical Specialty" field. This is an exact field. It has been indexed that is an 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, 862.1D through 892.1D). The classification regulation covers various aspects of design, clinical evaluation, manufacturing, marketing, labeling, and postmarketing surveillance of the specific medical device.