Section	Field Name	Type	Description
	regulation_number	string	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. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Fore more information, see CFR database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm).
	life_sustain_support_flag	string	An indicator that the device is essential to, or yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life. Value is one of the following Y = Device is used for life sustaining purposes. N = Device is not used for life sustaining purposes
	definition	string	Compositional definition of a medical device, based on the input of nomenclature experts, incorporating the definition of components of a device.
	review_code	string	Documentation forthcoming.
	submission_type_id		The submission type (510(k), PMA, 510(k) Exempt) to which a product code is limited, or "Contact ODE" if its limitations (if any) are undetermined. Value is one of the following 1 = 510(K) 2 = PMA 3 = Contact ODE 4 = 510(K) Exempt
	third_party_flag	string	Eligibility for a manufacturer to utilize a contracted Accredited Person in lieu of direct submission to FDA. By law, FDA must in turn issue a final determination within 30 days after receiving the recommendation of an Accredited Person (yielding a streamlined review process). Value is one of the following Y = Device is a candidate for a third party review program
	implant_flag	string	An indicator that the device is placed into a surgically or naturally formed cavity of the human body. Intended to remain implanted for 30 days or more; or the Commissioner makes a determination (that the device is to be considered implanted). Value is one of the following Y = Device is implantable N = Device is not implantable
	medical_specialty	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. Two letters indicating the medical specialty panel responsible for reviewing the product. See link for further detail. Value is one of the following AN = Anesthesiology CV = Cardiovascular CH = Clinical Chemistry DE = Dental EN = Ear, Nose, Throat GU = Gastroenterology, Urology HO = General Hospital HE = Hematology IM = Immunology MG = Medical Genetics MI = Microbiology NE = Neurology OB = Obstetrics/Gynecology OP = Ophthalmic OR = Orthopedic PA = Pathology PM = Physical Medicine RA = Radiology SU = General, Plastic Surgery TX = Clinical Toxicology
	medical_specialty_description	string	Same as above but with the codes replaced with a human readable description. Note that & and and have been removed from the descriptions as they conflicted with the API syntax). This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	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
	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.
	product_code	string	A three-letter identifier assigned to a device category. Assignment is based upon the medical device classification designated under 21 CFR Parts 862-892, and the technology and intended use of the device. Occasionally these codes are changed over time.
	review_panel	string	Known as the "510(k) Review Panel" since 2014, this helps define the review division within CDRH in which the 510(k) would be reviewed, if it were reviewed today; this is derived from the procode and is always the same as the "Review Advisory Committee" field in the 510(k) database.
	unclassified_reason	string	This indicates the reason why a device is unclassified (e.g. Pre-Amendment). Value is one of the following 1 = Pre-Amendment 2 = IDE 3 = For Export Only 4 = Unknown 5 = Guidance Under Development 6 = Enforcement Discretion 7 = Not FDA Regulated
	gmp_exempt_flag	string	An indication the device is exempt from Good Manufacturing Processes CFR 820. U.S. zip code of the Applicant. See here for more detail. Value is one of the following Y = Exempt due to Good Manufacturing Practice (GMP)/Quality System N = Not exempt due to Good Manufacturing Practice (GMP)/Quality System
OpenFDA fields	fei_number	array of strings	Facility identifier assigned to facility by the FDA Office of Regulatory Affairs. The openfda section of each document is determined by looking at the product_code value.
OpenFDA fields	registration_number	array of strings	