Section	Field Name	Type	Description
	k_number	string	FDA-assigned premarket notification number, including leading letters. Leading letters “BK” indicates 510(k) clearance, or Premarket Notification, cleared by Center for Biologics Evaluation and Research. Leading letters “DEN” indicates De Novo, or Evaluation of Automatic Class III Designation. Leading letter “K” indicates 510(k) clearance, or Premarket Notification. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	clearance_type	string	Denotes the submission method utilized for the submission of the 510(k). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following traditional = Traditional special = Special post = Post nse = NSE direct = Direct track = Track dual = Dual
	zip_code	string	Portion of address that designates the U.S. zip code of applicant.
	decision_code	string	Four letter codes that denote the specific substantial equivalence decision rendered by FDA on a specific 510(k). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following SEKD = Substantially Equivalent - Kit with Drugs SESD = Substantially Equivalent with Drug SESE = Substantially Equivalent SESK = Substantially Equivalent - Kit SESP = Substantially Equivalent - Postmarket Surveillance Required SESU = Substantially Equivalent - With Limitations SESR = Potential Recall
	decision_description	string	This is the full spelling associated with the abbreviated decision code (e.g. Substantially Equivalent - Postmarket Surveillance Required).
	statement_or_summary	string	A statement or summary can be provided per 21 CFR 807.3(n) and (o). A 510(k) summary, submitted under section 513(i) of the act, of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based. Safety and effectiveness information refers to safety and effectiveness data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness. The 510(k) Statement is a statement, made under section 513(i) of the act, asserting that all information in a premarket notification submission regarding safety and effectiveness will be made available within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information to be made available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret or confidential commercial information, as defined in 21 CFR 20.61. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	date_received	string	Date that the FDA Document Control Center received the submission.
	third_party_flag	string	Eligibility for a manufacturer to utilize a contracted Accredited Person in lieu of direct submission to FDA yielding a streamlined review process. Criteria in section 523(b)(3) of 21 U.S.C. 360m(b). Value is one of the following Y = Yes N = No
	state	string	This is the state of record of U.S. based applicants. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	address_1	string	Delivery address of the applicant.
	address_2	string	Delivery address of the applicant.
	contact	string	Per 21 CFR 807.3(e), this is the official correspondent designated by the owner or operator of an establishment as responsible for the following: (1) The annual registration of the establishment and (2) Contact with the Food and Drug Administration for device listing; and (3) Maintenance and submission of a current list of officers and directors to the Food and Drug Administration upon the request of the Commissioner; and (4) The receipt of pertinent correspondence from the Food and Drug Administration directed to and involving the owner or operator and/or any of the firm’s : establishments; and (5) The annual certification of medical device reports required by 804.30 of this chapter or forwarding the certification form to the person designated by the firm as responsible for the certification. For 510ks received before Aug 14, 2014, this could be either the contact from the manufacturer who submitted the 510k, the third party OR the consultant; after Aug 14, 2014, it is always the Applicant (manufacturer) This is an .exact field. It has been indexed both as its exact string content, and also tokenized.

	country_code	string	The numeric 2 character code (ISO 3166-1 alpha-2) that designates the country of a postal delivery location (also known as country code). This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	city	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
	review_advisory_committee	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 Panel” field in the Device Classification database.
	advisory_committee	string	Code under which the product was originally classified, based on the product code. This is a historical designation for the group that initially placed a device into Class I, Class II, or Class III following the medical device amendments of May 28, 1976. Two letters indicate the medical specialty panel that was responsible for classifying the product (e.g. GU). This is an .exact field. It has been indexed both as its exact string content, and also tokenized. 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 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
	advisory_committee_description	string	Full spelling of the Advisory Committee abbreviation (e.g. Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee). (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_name	string	This is the proprietary name of the cleared device (trade name). 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.
	postal_code	string	A series of letters and/or digits, sometimes including spaces or punctuation, included in a postal address for the purpose of sorting mail. In the United States, this is a Zip code (below). This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	applicant	string	The manufacturer of record or third party who submits a 510(k) submission. Also known as sponsor. Please note, before Aug 14, 2014, this could be either the manufacturer who submitted the 510k, the third party OR the consultant; after Aug 14, 2014, it is always the manufacturer. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
	decision_date	string	This is the date on which FDA rendered a final decision on a 510(k) submission.

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	array of strings	Facility identifier assigned to facility by the FDA Office of Regulatory Affairs.
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	registration_number	array of strings	
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.