Section	Field Name	Type	Description
Event	adverse_event_flag	string	Whether the report is about an incident where the use of the device is suspected to have resulted in an adverse outcome in a patient. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Y = Yes N = No
Event	product_problems	array of strings	The product problems that were reported to the FDA if there was a concern about the quality, authenticity, performance, or safety of any medication or device.
Event	product_problem_flag	string	Indicates whether or not a report was about the quality, performance or safety of a device. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Y = The report is about the quality, performance, or safety of a device—for example, defects or malfunctions. This flag is set when a device malfunction could lead to a death or serious injury if the malfunction were to recur. N = The report is not about a defect or malfunction.
Event	date_of_event	string	Actual or best estimate of the date of first onset of the adverse event. This field was added in 2006.
Event	date_report	string	Date the initial reporter (whoever initially provided information to the user facility, manufacturer, or importer) provided the information about the event.
Event	date_received	string	Date the report was received by the FDA.
Event	device_date_of_manufacturer	string	Date of manufacture of the suspect medical device.
Event	event_type	string	Outcomes associated with the adverse event. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Death = Death, either caused by or associated with the adverse event. Injury (IN) = Documentation forthcoming. Injury (IL) = Documentation forthcoming. Injury (IJ) = Documentation forthcoming. Malfunction = Product malfunction. Other = Other serious/important medical event. No answer provided = No information was provided.
Event	number_devices_in_event	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 both as its exact string content, and also tokenized.
Event	number_patients_in_event	string	Number of patients 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 both as its exact string content, and also tokenized.
Event	previous_use_code	string	Whether the use of the suspect medical device was the initial use, reuse, or unknown. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following I = Initial use. R = Reuse. U = Unknown. * = Invalid data or this information was not provided.
Event	remedial_action	array of strings	Follow-up actions taken by the device manufacturer at the time of the report submission, if applicable. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Recall = Recall Repair = Repair Replace = Replace Relabeling = Relabeling Other = Other Notification = Notification Inspection = Inspection Patient Monitoring = Patient Monitoring Modification/Adjustment = Modification/Adjustment Invalid Data = Invalid Data
Event	removal_correction_number	string	If a corrective action was reported to FDA under 21 USC 360i(f), the correction or removal reporting number (according to the format directed by 21 CFR 807). If a firm has not submitted a correction or removal report to the FDA, but the FDA has assigned a recall number to the corrective action, the recall number may be used. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Event	report_number	string	Identifying number for the adverse event report. The format varies, according to the source of the report. The field is empty when a user facility submits a report. For manufacturer reports. Manufacturer Report Number. The report number consists of three components: The manufacturer's FDA registration number for the manufacturing site of the reported device, the 4-digit calendar year, and a consecutive 5-digit number for each report filed during the year by the manufacturer (e.g. 1234567-2013-00001, 1234567-2013-00002). For user facility/importer (distributor) reports. Distributor Report Number. Documentation forthcoming. For consumer reports. This field is empty. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Event	single_use_flag	string	Whether the device was labeled for single use or not. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Yes = The device was labeled for single use. No = The device was not labeled for single use, or this is irrelevant to the device being reported (e.g. an X-ray machine).
Source	report_source_code	string	Source of the adverse event report This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Manufacturer report = Manufacturer report Voluntary report = Voluntary report User facility report = User facility report Distributor report = Distributor report
Source	health_professional	string	Whether the initial reporter was a health professional (e.g. physician, pharmacist, nurse, etc.) or not. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Y = The initial reporter is a health professional. N = The initial reporter is not a health professional.
Source	reporter_occupation_code	string	Initial reporter occupation. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Physician = Physician Nurse = Nurse Health professional = Health professional Lay user/patient = Lay user/patient Other health care professional = Other health care professional Audiologist = Audiologist Dental hygienist = Dental hygienist Dietician = Dietician Emergency medical technician = Emergency medical technician Medical technologist = Medical technologist Nuclear medicine technologist = Nuclear medicine technologist Occupational therapist = Occupational therapist Paramedic = Paramedic Pharmacist = Pharmacist Phlebotomist = Phlebotomist Physical therapist = Physical therapist Physician assistant = Physician assistant Radiologic technologist = Radiologic technologist Respiratory therapist = Respiratory therapist Speech therapist = Speech therapist Dentist = Dentist
Source	initial_report_to_fda	string	Whether the initial reporter also notified or submitted a copy of this report to FDA. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Yes = FDA was also notified by the initial reporter. No = FDA was not notified by the initial reporter. Unknown = Unknown whether FDA was also notified by the initial reporter. No answer provided or empty = This information was not provided.
Source	reprocessed_and_reused_flag	string	Indicates whether the suspect device was a single-use device that was reprocessed and reused on a patient. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Y = Was a single-use device that was reprocessed and reused. N = Was not a single-use device that was reprocessed and reused. UNK = The original equipment manufacturer was unable to determine if their single-use device was reprocessed and reused.

Device	device.device_sequence_number	string	Number identifying this particular device. For example, the first device object will have the value 1. This is an enumeration corresponding to the number of patients involved in an adverse event. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Device	device.device_event_key	string	Documentation forthcoming.
Device	device.date_received	string	Documentation forthcoming.
Identification	device.brand_name	string	The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog (e.g. Flo-Easy Catheter, Reliable Heart Pacemaker, etc.). If the suspect device is a reprocessed single-use device, this field will contain NA. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Identification	device.generic_name	string	The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.). This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Identification	device.udi_di	string	A unique numeric or alphanumeric code specific to a device version or model.
Identification	device.udi_public	string	Includes both the UDI-DI and the parts of the Production Identifier (PI) that would not identify an individual patient. The Production Identifier is a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device and may include: 1) lot or batch number within which a device was manufactured, 2) serial number of a specific device, 3) expiration date of a specific device, 4) date a specific device was manufactured, and 5) distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.
Identification	device.device_report_product_code	string	Three-letter FDA Product Classification Code. Medical devices are classified under 21 CFR Parts 862-892. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Fore more information, see Product Classification Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm)
Identification	device.model_number	string	The exact model number found on the device label or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Identification	device_catalog_number	string	The exact number as it appears in the manufacturer's catalog, device labeling, or accompanying packaging. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Identification	device.lot_number	string	If available, the lot number found on the label or packaging material. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Identification	device.other_id_number	string	Any other identifier that might be used to identify the device. Expect wide variability in the use of this field. It is commonly empty, or marked NA, N/A, *, or UNK, if unknown or not applicable. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Identification	device.expiration_date_of_device	string	If available; this date is often be found on the device itself or printed on the accompanying packaging.
Identification	device.device_age_text	string	Age of the device or a best estimate, often including the unit of time used. Contents vary widely, but common patterns include: ## Mo or ## Yr (meaning number of months or years, respectively.
Identification	device.device_availability	string	Whether the device is available for evaluation by the manufacturer, or whether the device was returned to the manufacturer. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Yes = Yes No = No Device was returned to manufacturer = Device was returned to manufacturer No answer provided = No answer provided I = Documentation forthcoming.
Identification	device.date_returned_to_manufacturer	string	Date the device was returned to the manufacturer, if applicable.
Identification	device.device_evaluated_by_manufacturer	string	Whether the suspect device was evaluated by the manufacturer. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Yes = An evaluation was made of the suspect or related medical device. No = An evaluation of a returned suspect or related medical device was not conducted. Device not returned to manufacturer = An evaluation could not be made because the device was not returned to, or made available to, the manufacturer. No answer provided or empty = No answer was provided or this information was unavailable.
Use of Device	device.device_operator	string	The person using the medical device at the time of the adverse event. This may be a health professional, a lay person, or may not be applicable. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Physician = Physician Nurse = Nurse Health professional = Health professional Lay user/patient = Lay user/patient Other health care professional = Other health care professional Audiologist = Audiologist Dental hygienist = Dental hygienist Dietician = Dietician Emergency medical technician = Emergency medical technician Medical technologist = Medical technologist Nuclear medicine technologist = Nuclear medicine technologist Occupational therapist = Occupational therapist Paramedic = Paramedic Pharmacist = Pharmacist Phlebotomist = Phlebotomist Physical therapist = Physical therapist Physician assistant = Physician assistant Radiologic technologist = Radiologic technologist Respiratory therapist = Respiratory therapist Speech therapist = Speech therapist Dentist = Dentist
Use of Device	device.implant_flag	string	Whether a device was implanted or not. May be either marked N or left empty if this was not applicable. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Use of Device	device.date_removed_flag	string	Whether an implanted device was removed from the patient, and if so, what kind of date was provided. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Month and year provided only day defaults to 01 = Only a year and month were provided. Day was set to 01. Year provided only = Only a year was provided. Month was set to 01 (January) and day set to 01. No information at this time = Documentation forthcoming. Not available = Documentation forthcoming. Unknown = Documentation forthcoming. * = Documentation forthcoming. B = Documentation forthcoming. V = Documentation forthcoming.
Manufacturer	device.manufacturer_d_name	string	Device manufacturer name. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_address_1	string	Device manufacturer address line 1. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_address_2	string	Device manufacturer address line 2. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_city	string	Device manufacturer city. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_state	string	Device manufacturer state code This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_zip_code	string	Device manufacturer zip code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_zip_code_ext	string	Device manufacturer zip code extension. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_postal_code	string	Device manufacturer postal code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Manufacturer	device.manufacturer_d_country	string	Device manufacturer country. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Patient	patient.date_received	string	Date the report about this patient was received.
Patient	patient.patient_sequence_number	string	Documentation forthcoming. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Patient	patient.patient_age	string	Patient's age. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Patient	patient.patient_sex	string	Patient's gender. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Patient	patient.patient_weight	string	Patient's weight. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Patient	patient.patient_ethnicity	string	Patient's ethnicity. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Patient	patient.patient_race	string	Patient's race. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Patient	patient.patient_problems	array of strings	Describes actual adverse effects on the patient that may be related to the device problem observed during the reported event. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.

Patient	patient.sequence_number_outcome	array of strings	Outcome associated with the adverse event for this patient. Expect wide variability in this field; each string in the list of strings may contain multiple outcomes, separated by commas, and with numbers, which may or may not be related to the patient_sequence_number. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Life Threatening = Life Threatening Hospitalization = Hospitalization Disability = Disability Congenital Anomaly = Congenital Anomaly Required Intervention = Required Intervention Other = Other Invalid Data = Invalid Data Unknown = Unknown No Information = No Information Not Applicable = Not Applicable Death = Death
Patient	patient.sequence_number_treatment	array of strings	Treatment the patient received. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Report text	mdr_text.date_report	string	Date the initial reporter (whoever initially provided information to the user facility, manufacturer, or importer) provided the information about the event.
Report text	mdr_text.mdr_text_key	string	Documentation forthcoming. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Report text	mdr_text.patient_sequence_number	string	Number identifying this particular patient. For example, the first patient object will have the value 1. This is an enumeration corresponding to the number of patients involved in an adverse event. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Report text	mdr_text.text	string	Narrative text or problem description. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Report text	mdr_text.text_type_code	string	String that describes the type of narrative contained within the text field. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Description of Event or Problem = The problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. For patient adverse events, may include a description of the event in detail using the reporter's own words, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, may include synopsis of any office visit notes or the hospital discharge summary. This section may also contain information about surgical procedures and laboratory tests. Manufacturer Evaluation Summary = If available, the results of any evaluation of a malfunctioning device and, if known, any relevant maintenance/service information should be included in this section. Additional Manufacturer Narrative = Documentation forthcoming.
By user facility/importer	type_of_report	string	The type of report. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Initial submission = Initial report of an event. Followup = Additional or corrected information. Extra copy received = Documentation forthcoming. Other information submitted = Documentation forthcoming.
By user facility/importer	date_facility_aware	string	Date the user facility's medical personnel or the importer (distributor) became aware that the device has or may have caused or contributed to the reported event.
By user facility/importer	report_date	string	Date of the report, or the date that the report was forwarded to the manufacturer and/or the FDA.
By user facility/importer	report_to_fda	string	Whether the report was sent to the FDA by a user facility or importer (distributor). User facilities are required to send reports of device-related deaths and serious injuries. Importers are required to send reports of device-related deaths and serious injuries. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Y = The report was sent to the FDA by a user facility or importer. N = The report was not sent to the FDA by a user facility or importer.
By user facility/importer	date_report_to_fda	string	Date the user facility/importer (distributor) sent the report to the FDA, if applicable.
By user facility/importer	report_to_manufacturer	string	Whether the report was sent to the manufacturer by a user facility or importer (distributor). User facilities are required to send reports of device-related deaths and serious injuries to manufacturers. Importers are required to send reports to manufacturers of device-related deaths, device-related serious injuries, and device-related malfunctions that could cause or contribute to a death or serious injury. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Y = The report was sent to the manufacturer by a user facility or importer. N = The report was not sent to the manufacturer by a user facility or importer.
By user facility/importer	date_report_to_manufacturer	string	Date the user facility/importer (distributor) sent the report to the manufacturer, if applicable.
By user facility/importer	event_location	string	Where the event occurred. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Other = Other Hospital = Hospital Home = Home Nursing home = Nursing home Outpatient treatment facility = Outpatient treatment facility Outpatient diagnostic facility = Outpatient diagnostic facility Ambulatory surgical facility = Ambulatory surgical facility Catheterization suite = Catheterization suite Critical care unit = Critical care unit Dialysis unit = Dialysis unit Emergency room = Emergency room Examination room = Examination room Laboratory/pathology department = Laboratory/pathology department Maternity ward - nursery = Maternity ward - nursery Operating room = Operating room Outpatient clinic/surgery = Outpatient clinic/surgery Patients room or ward = Patients room or ward Radiology department = Radiology department Ambulatory health care facility = Ambulatory health care facility Ambulatory surgical center = Ambulatory surgical center Blood bank = Blood bank
Name and address	distributor_name	string	User facility or importer (distributor) name. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address	distributor_address_1	string	User facility or importer (distributor) address line 1. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address	distributor_address_2	string	User facility or importer (distributor) address line 2. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address	distributor_city	string	User facility or importer (distributor) city. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address	distributor_state	string	User facility or importer (distributor) two-digit state code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address	distributor_zip_code	string	User facility or importer (distributor) 5-digit zip code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Name and address	distributor_zip_code_ext	string	User facility or importer (distributor) 4-digit zip code extension (zip+4 code). This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_name	string	Suspect medical device manufacturer name. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_address_1	string	Suspect medical device manufacturer address line 1. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_address_2	string	Suspect medical device manufacturer address line 2. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_city	string	Suspect medical device manufacturer city. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_postal_code	string	Suspect medical device manufacturer postal code. May contain the zip code for addresses in the United States. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_state	string	Suspect medical device manufacturer two-letter state code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_zip_code	string	Suspect medical device manufacturer 5-digit zip code. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.

Suspect device manufacturer	manufacturer_zip_code_ext	string	Suspect medical device manufacturer 4-digit zip code extension (zip+4 code).
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_country	string	Suspect medical device manufacturer two-letter country code. Note: For medical device adverse event reports, comparing country codes with city names in the same record demonstrates widespread use of conflicting codes. Caution should be exercised when interpreting country code data in device records.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_address_1	string	Suspect medical device manufacturer contact address line 1.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_address_2	string	Suspect medical device manufacturer contact address line 2.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_area_code	string	Manufacturer contact person phone number area code.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_city	string	Manufacturer contact person city.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_country	string	Manufacturer contact person two-letter country code. Note: For medical device adverse event reports, comparing country codes with city names in the same record demonstrates widespread use of conflicting codes. Caution should be exercised when interpreting country code data in device records.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_exchange	string	Manufacturer contact person phone number exchange.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_extension	string	Manufacturer contact person phone number extension.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_t_name	string	Manufacturer contact person title (Mr., Mrs., Ms., Dr., etc.)
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_f_name	string	Manufacturer contact person first name.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_l_name	string	Manufacturer contact person last name.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_pcity	string	Manufacturer contact person phone number city code.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_pcountry	string	Manufacturer contact person phone number country code. Note: For medical device adverse event reports, comparing country codes with city names in the same record demonstrates widespread use of conflicting codes. Caution should be exercised when interpreting country code data in device records.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_phone_number	string	Manufacturer contact person phone number.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_plocal	string	Manufacturer contact person local phone number.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_postal_code	string	Manufacturer contact person postal code.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_state	string	Manufacturer contact person two-letter state code.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_zip_code	string	Manufacturer contact person 5-digit zip code.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_contact_zip_ext	string	Manufacturer contact person 4-digit zip code extension (zip+4 code).
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_g1_name	string	Device manufacturer name.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_g1_city	string	Device manufacturer address city.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_g1_country	string	Device manufacturer two-letter country code. Note: For medical device adverse event reports, comparing country codes with city names in the same record demonstrates widespread use of conflicting codes. Caution should be exercised when interpreting country code data in device records.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_g1_postal_code	string	Device manufacturer address postal code.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_g1_state	string	Device manufacturer address state.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_g1_address_1	string	Device manufacturer address line 1.
Suspect device manufacturer	manufacturer_g1_address_2	string	Device manufacturer address line 2.
Suspect device manufacturer	manufacturer_g1_zip_code	string	Device manufacturer address zip code.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Suspect device manufacturer	manufacturer_g1_zip_code_ext	string	Device manufacturer address zip code extension.
			This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
By any manufacturer	date_manufacturer_received	string	Date when the applicant, manufacturer, corporate affiliate, etc. receives information that an adverse event or medical device malfunction has occurred. This would apply to a report received anywhere in the world. For follow-up reports, the date that the follow-up information was received.
By any manufacturer	source_type	string	The manufacturer-reported source of the adverse event report. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Other = Other Foreign = Foreign Study = Study Literature = Literature Consumer = Consumer Health Professional = Health Professional User facility = User facility Company representation = Company representation Distributor = Distributor Unknown = Unknown Invalid data = Invalid data
Keys and flags	event_key	string	Documentation forthcoming. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Keys and flags	mdr_report_key	string	A unique identifier for a report. This key is part of the download files and is used to join the four files together. This is an .exact field. It has been indexed both as its exact string content, and also tokenized.
Keys and flags	manufacturer_link_flag	string	Indicates whether a user facility/importer-submitted (distributor-submitted) report had had subsequent manufacturer-submitted reports. If so, the distributor information (address, etc.) will also be present and this field will contain Y. This is an .exact field. It has been indexed both as its exact string content, and also tokenized. Value is one of the following Y = There are subsequent manufacturer-submitted reports. N = There are no subsequent manufacturer-submitted reports.
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.