<table>
<thead>
<tr>
<th>Field Name</th>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>registration_number</td>
<td>string</td>
<td>The classification regulation in the Code of Federal Regulations (CFR) under which the device is classified, described, and formally classified (Code of Federal Regulations Title 21, 820.30 through 892.30). 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. For more information, see CFR database (<a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfreg/CFReg.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfreg/CFReg.cfm</a>).</td>
</tr>
</tbody>
</table>
| fei_number                      | 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: 
N = Device is not exempt due to Good Manufacturing Practice (GMP)/Quality System 
Y = Device is exempt due to Good Manufacturing Practice (GMP)/Quality System 
Value is one of the following: 
# = Value is undetermined |
| unclassified_reason             | string   | This indicates the reason why a device is unclassified (e.g. Pre-Amendment). Two letters indicating the medical specialty panel responsible for reviewing the product. See link for further detail. |
| 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. Occasionally these codes are changed over time. |
| 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. |
| device_name                     | string   | A risk based classification system for all medical devices. The classification system is based on the input of nomenclature experts, incorporating the definition of components of a device. |
| submission_type_id              | string   | 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: 
Eligible = 510(k) 
Ineligible = PMA |
| submission_control_reporting    | string   | 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: 
Eligible = 510(k) 
Ineligible = PMA |
| third_party_flag                | string   | An indicator that the device is a candidate for a third party review program |
| medical_specialty              | string   | Regulation Medical Specialty is assigned based on the regulation (e.g. 21 CFR Part 888 is Orthopedic Devices) which is why only a few devices lack the “Regulation Medical Specialty” field. Two letters indicating the medical specialty panel responsible for reviewing the product. See link for further detail. |
| medical_specialty_description   | string   | Same as above (but with the codes replaced with a human readable description. Note that & and / have been removed from the descriptions as they conflicted with the AR syntax). |
| medical_device                 | string   | This is the proprietary name, or trade name, of the cleared device |
| device_type                    | string   | This is the proprietary name, or trade name, of the cleared device |
| implant_flag                   | string   | An indicator that the device is implanted (Code of Federal Regulations Title 21, 801.50 through 801.57). The classification regulation covers various aspects of design, clinical evaluation, manufacturing, packaging, labeling, and postmarket surveillance of the specific medical device (21 CFR Parts 801.50 through 801.57). This is an exact field. It has been indexed both as its exact string content, and also tokenized. |
| life_sustain_support_flag      | string   | An indicator that the device is used for life sustaining purposes. Value is one of the following: 
N = Device is not used for life sustaining purposes |
| submission_control_reporting    | string   | 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: 
Eligible = 510(k) 
Ineligible = PMA |
| potential_issue                | 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 = IDE Exempt Only 
4 = Unknown 
5 = Guidance Under Development 
6 = Enforcement Discretion 
7 = Not FDA Regulated |
| summary_malfunction_reporting  | string   | This is a standardized field that identifies the principal malfunction(s) and the composed malfunction(s) of the medical device, based on the input of nomenclature experts, incorporating the definition of component(s) of a device. |
| registration_number            | string   | An indicator that the device is exempt from Good Manufacturing Processes CFR 820. U.S. zip code of the Applicant. See link for further detail. |
| documentation_filing           | string   | This is an exact field. It has been indexed both as its exact string content, and also tokenized. |
| classification_filing          | string   | This is an exact field. It has been indexed both as its exact string content, and also tokenized. |
| summary_malfunction_reporting  | string   | This is an exact field. It has been indexed both as its exact string content, and also tokenized. |
| documentation_filing           | string   | This is an exact field. It has been indexed both as its exact string content, and also tokenized. |
| potential_issue                | 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 = IDE Exempt Only 
4 = Unknown 
5 = Guidance Under Development 
6 = Enforcement Discretion 
7 = Not FDA Regulated |
| medical_device                 | string   | A risk based classification system for all medical devices. The classification system is based on the input of nomenclature experts, incorporating the definition of components of a device. |
| device_type                    | string   | This is the proprietary name, or trade name, of the cleared device |
| device_name                     | string   | This is the proprietary name, or trade name, of the cleared device |
| implant_flag                   | string   | An indicator that the device is implanted (Code of Federal Regulations Title 21, 801.50 through 801.57). The classification regulation covers various aspects of design, clinical evaluation, manufacturing, packaging, labeling, and postmarket surveillance of the specific medical device (21 CFR Parts 801.50 through 801.57). This is an exact field. It has been indexed both as its exact string content, and also tokenized. |
| submission_type_id              | string   | 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: 
Eligible = 510(k) 
Ineligible = PMA |
| medical_specialty              | string   | Regulation Medical Specialty is assigned based on the regulation (e.g. 21 CFR Part 888 is Orthopedic Devices) which is why only a few devices lack the “Regulation Medical Specialty” field. Two letters indicating the medical specialty panel responsible for reviewing the product. See link for further detail. |
| medical_specialty_description   | string   | Same as above (but with the codes replaced with a human readable description. Note that & and / have been removed from the descriptions as they conflicted with the AR syntax). |
| medical_device                 | string   | This is the proprietary name, or trade name, of the cleared device |
| device_type                    | string   | This is the proprietary name, or trade name, of the cleared device |
| implant_flag                   | string   | An indicator that the device is implanted (Code of Federal Regulations Title 21, 801.50 through 801.57). The classification regulation covers various aspects of design, clinical evaluation, manufacturing, packaging, labeling, and postmarket surveillance of the specific medical device (21 CFR Parts 801.50 through 801.57). This is an exact field. It has been indexed both as its exact string content, and also tokenized. |
| submission_type_id              | string   | 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: 
Eligible = 510(k) 
Ineligible = PMA |
| medical_specialty              | string   | Regulation Medical Specialty is assigned based on the regulation (e.g. 21 CFR Part 888 is Orthopedic Devices) which is why only a few devices lack the “Regulation Medical Specialty” field. Two letters indicating the medical specialty panel responsible for reviewing the product. See link for further detail. |
| medical_specialty_description   | string   | Same as above (but with the codes replaced with a human readable description. Note that & and / have been removed from the descriptions as they conflicted with the AR syntax). |
| medical_device                 | string   | A risk based classification system for all medical devices. The classification system is based on the input of nomenclature experts, incorporating the definition of components of a device. |
| device_type                    | string   | This is the proprietary name, or trade name, of the cleared device |
| implant_flag                   | string   | An indicator that the device is implanted (Code of Federal Regulations Title 21, 801.50 through 801.57). The classification regulation covers various aspects of design, clinical evaluation, manufacturing, packaging, labeling, and postmarket surveillance of the specific medical device (21 CFR Parts 801.50 through 801.57). This is an exact field. It has been indexed both as its exact string content, and also tokenized. |
| submission_type_id              | string   | 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: 
Eligible = 510(k) 
Ineligible = PMA |
| medical_specialty              | string   | Regulation Medical Specialty is assigned based on the regulation (e.g. 21 CFR Part 888 is Orthopedic Devices) which is why only a few devices lack the “Regulation Medical Specialty” field. Two letters indicating the medical specialty panel responsible for reviewing the product. See link for further detail. |
| medical_specialty_description   | string   | Same as above (but with the codes replaced with a human readable description. Note that & and / have been removed from the descriptions as they conflicted with the AR syntax). |