|  |  |
| --- | --- |
|  | New DI Trigger Field |
|  |  |
|  | Auto-populated Field |
|  |  |
| ¥ | Publicly released Field[[1]](#footnote-1) |
|  |  |
| **\*** | Required Field[[2]](#footnote-2) |

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| **DEVICE INFORMATION** | | | | | | | | | | | | |
| **Device Identifier (DI) Information** | | | | | | | | | | | | |
| Issuing Agency**\***¥:  Choose Issuing Agency | Primary DI Number**\***¥: | | | | | Device Count**\***¥: | | | | | | Unit of Use DI Number¥: |
| Labeler DUNS Number**\***: | Company Name¥: | | | | | Company Physical Address: | | | | | | |
| Brand Name**\***¥: | | | | Version or Model Number**\***¥: | | | | Catalog Number¥: | | | | |
| Device Description (max 2000 characters)¥: | | | | | | | | | | | | |
| **Commercial Distribution** | | | | | | | | | | | | |
| DI Record Publish Date (yyyy-mm-dd)**\*** ¥:  Choose date | | Commercial Distribution End Date (yyyy-mm-dd)**\*** ¥:  Choose date | | | | | | | Commercial Distribution Status¥:  Choose Status | | | |
| **Alternative and Additional Identifiers** | | | | | | | | | | | | |
| **Direct Marking (DM)** | | | | |  | **Secondary DI *(if applicable)*** | | | | | | |
| Device Subject to Direct Marking (DM), but Exempt¥ | | | | | Issuing Agency¥:  Choose Issuing Agency | | | | Secondary DI Number¥: | | |
| DM DI Different from Primary DI¥  DM DI Number¥: | | | | | *<add Secondary DI if needed>* | | | | | | |
| **Previous DI *(if applicable)*** | | | | | | |
| Issuing Agency¥:  Choose Issuing Agency | | | | Previous DI Number¥: | | |
| *<add Previous DI if needed>* | | | | | | |
| **Package DI** | | | | | | | | | | | | |
| Package DI Number¥: | Quantity per Package¥: | | Contains DI Package¥: | | Package Type¥: | | Package Discontinue Date¥:  Choose date | | | | Package Status¥:  Choose Status | |
| *<add Package DI if needed>* | | | | | | | | | | | | |
| **Customer Contact** | | | | | | | | | | | | |
| Customer Contact Phone¥: | | | | | | Customer Contact Email¥: | | | | | | |

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| **DEVICE STATUS** | | | | | | | | | | | | | | |
| Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) ¥ | | | | | | | | | | | Kit¥ | | Combination Product¥ | |
| **Premarket** | | | | | | |  | **FDA Product Code** | | | | | | |
| Device Exempt from Premarket Submission¥ | | | | | | |
| FDA Premarket Submission Number: | | | | Supplement Number: | | | Product Code¥: | | Product Code Name¥: | | | | |
|  | | | | | | | | | | | | | | |
| **FDA Listing** | |  | **GMDN** | | | | | | | | | | | |
| FDA Listing Number: | | Code: | | Name¥: | | | | | Definition¥: | | | | |
|  | | | | | | | | | | | | | | |
| **DEVICE CHARACTERISTICS** | | | | | | | | | | | | | | |
| For Single-Use**\***¥:  Choose |
| **Production Identifier(s) in UDI** | | | | | | |  | **Latex Information** | | | | | | |
| Lot or Batch Number**\***¥:  Choose  Serial Number**\***¥:  Choose  Expiration Date**\***¥:  Choose  Manufacturing Date**\***¥:  Choose  Donation Identification Number**\***¥:  Choose | | | | | | | Device required to be labeled as containing natural rubber later or dry natural rubber  (21 CFR 801.437)**\*** ¥:  Choose  Device labeled as “Not made with natural rubber latex” ¥ | | | | | | |
| **Prescription Status** | | | | | | |  | **MRI Safety** | | | | | |  |
| Prescription Use (Rx) ¥  Over the Counter (OTC) ¥ | | | | | | | What MRI safety information does the labeling contain? **\***¥:  Choose | | | | | | |
| **Clinically Relevant Size** | | | | | | | | | | | | | | |
| Size Type¥:  Choose | | | | | | Size Value¥: | | | | | | Size Unit of Measure¥: | | |
| *<add Size if needed>* | | | | | | | | | | | | | | |
| **Storage and Handling** | | | | | | | | | | | | | | |
| Storage and Handling Type¥:  Special Storage Conditions, Specify | | | | | | Low Value¥: | | | High Value¥: | | | Unit of Measure¥: | | |
| *<add Storage and Handling if needed>* | | | | | | | | | | | | | | |
| Special Storage Conditions (max 200 characters), only if “Special Storage Conditions” is selected above¥: | | | | | | | | | | | | | | |
| **Sterilization** | | | | | | | | | | | | | | |
| Device Packaged as Sterile**\***¥:  Choose | | | | | | Requires Sterilization Prior to Use**\***¥:  Choose | | | | | | If Yes, Sterilization Method¥:  Choose Sterilization Method | | |

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| **DI RECORD APPROVAL** | |
| DI Record can be submitted to GUDID  **GUDID Account Regulatory Contact** | |
| Name (Print): | *Signature & Date:* |
| **GUDID Account Coordinator(s)** | |
| Name (Print): | *Signature & Date:* |
| Name (Print): | *Signature & Date:* |
| Name (Print): | *Signature & Date:* |

1. Indicates data element values that are released to the public on AccessGUDID and OpenFDA. [↑](#footnote-ref-1)
2. See [GUDID Data Elements Reference Table](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396592.xls) for more details about the GUDID Business Rules and Guidelines. [↑](#footnote-ref-2)