Medical Device and Medical Supply Name and Primary Device Identifier Dataset Instructions Calendar Year 2026

Introduction

The Medical Device and Medical Supply Name and Primary Device Identifier Dataset is a reference tool for Applicable Manufacturers and Applicable Group Purchasing Organizations (AM/GPOs), collectively referred to as reporting entities, to validate Medical Device Name and primary device identifier (PDI) information before reporting payments to the Open Payments system. This reference data includes medical device and medical supply name and PDI information for all the medical devices and medical supplies listed in the Food and Drug Administration (FDA) Global Unique Device Identification Database Directory (GUDID) through December 31,2025.

How to use the Medical Device and Medical Supply Name and Primary Device Identifier Reference Data

The Medical Device and Medical Supply Name and Primary Device Identifier Reference Dataset is intended to be used as a reference when creating payment records for submission to the Open Payments system. It can be used to fill in missing information for a specific medical device or a medical supply associated with a payment or to validate medical device or medical supply information that the reporting entity has already collected. Beginning in Program Year 2022, information relating to medical device and medical supply name and PDI must match the CMS-approved dataset in order for the record to be submitted in the Open Payments system. Records that contain a medical device or medical supply name and PDI combination that does not match the CMS-approved dataset will not be able to be submitted.

This reference dataset is not a complete list of all medical devices and medical supplies; it contains only information collected by the FDA through December 31, 2025.

Medical devices or medical supplies that do not appear in the Medical Device and Medical Supply Name and Primary Device Identifier Dataset may still be collected/reported with a payment record. To submit a medical device or medical supply name that is not included in the Open Payments dataset, leave the “Primary Device Identifier” field blank.

According to the Final Rule, reporting entities may report up to a total of five covered / non-covered drugs, medical devices, biologicals, or medical supplies related to each general and/or research payment or transfer of value. For covered medical devices and medical supplies, reporting entities must report the marketed or brand name under which the medical device or medical supply is or was marketed. If the device has a unique device identifier (UDI), then the device identifier (DI) portions of it must be reported, as applicable (See 42 C.F.R. § 403.904(f)(1)(iv)).

If the payment or transfer of value is related to multiple devices/ medical supply products, the reporting entity may report up to five products. Each product may be reported with a combination of the Marketed Name of Drug, Device, Biological, or Medical Supply and the PDI on each general and/ or research payment or transfer of value. PDI information is from the FDA website as of December 31, 2025. At the end of every year, CMS will update the resource file as per the FDA GUDID active list. The historical PDI information will be maintained in the Open Payments system; if a user reports the previous PDI, the Open Payments system will recognize and validate successfully.

Contents of the Medical Device and Supply Name and Primary Device Identifier Reference Data

1. Medical Device and Medical Supply Name and Primary Device Identifier Reference Data file:

The Medical Device and Medical Supply Name and Primary Device Identifier Reference Data is delivered in one pipe-delimited .csv file. The file contains the following medical device information:

- **PrimaryDI** (Column A): The unique numeric or alphanumeric code specific to a device version or model, per the FDA website.
    - In the Open Payments application, this element corresponds to the "Primary Device Identifier" field for PY2021 onwards submissions.
- **BrandName** (Column B): The name of the medical device or medical supply chosen by the labeler.
    - In the Open Payments application, this element corresponds to the "Marketed Name of Drug, Device, Biological, or Medical Supply" field for PY2021 onwards submissions.

PDIs are required to be included for all medical device and medical supply that have PDIs. If the reported medical device or medical supply does not have a PDI, this field may be left blank. The combination of medical device or supply name and any PDI(s) entered must match the CMS approved dataset. To see more details about data submission, refer to the Open Payments

User Guide for Reporting Entities available on the Resources page of the Open Payments website (https://www.cms.gov/OpenPayments/Resources).

2. Cleansing rules applied while creating CSV files:

The following cleansing rules are applied to the medical supply name and PDI values against the CMS-approved dataset:

- Consecutive spaces reduced to one space in-between words
- Leading and trailing spaces removed
- Special characters are not permitted in the Open Payments system such as ®, ™, etc. or their equivalent symbol codes are removed. Only standard keyboard special characters are permitted in the Open Payments system.
- Umlauts are converted to US keyboard characters, (e.g. À is converted to A, È is converted to E, and Ø is converted to O). Users should convert the umlauts if present in the Brand Name or PDI value before submitting the device information into the Open Payments system to avoid validation error due to special characters.

3. Considerations for using the CSV Files:

- Microsoft Excel removes leading zeroes from data fields in CSV files. Certain fields in these data sets may have leading zeroes. These zeroes will be missing when viewing the information within Microsoft Excel. To avoid this, it is recommended to set the format of the fields containing leading zeroes to "Text" instead of "Number" before importing the data file.

- The latest versions of Microsoft Excel cannot display data sets with more than 1,048,576 rows, and this CSV file may exceed that limit. Displaying the data in its entirety may require the use of spreadsheet programs capable of handling a very large number of records. If the version of the Microsoft Excel is 2003 or lower, consider downloading the data file and use the import feature of Microsoft Excel. In the scenario that the file is too large, it is recommended to split the file into multiple files before opening into Excel.

- As an alternative, a program such as Universal Viewer or Editpad Lite can be used to open the file.

If a Medical Device or Medical Supply is Not Found in the Reference Data

Medical Devices or Medical Supplies that do not appear in the Medical Device and Medical Supply Name and Primary Device Identifier Dataset may still be submitted with a payment record. When submitting medical devices or medical supplies that are not listed in the Medical Device and Medical Supply Name and Primary Device Identifier Dataset, leave the "Primary Device Identifier" field blank in order for it to be recognized and validated successfully in the Open Payments System. Information on new devices and supplies listed in the FDA GUDID Directory after December 31, 2025, may be found in the List of Medical Device or Medical Supply Names and Primary Device Identifier Directory at https://accessgudid.nlm.nih.gov/download/delimited.

Disclosure

- **Disclaimer**: The contents of this document do not have the force and effect of law and are not meant to bind the public in any way unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

- **Activities/persons addressed by this document**: Guidance includes a medical device and medical supply names and Primary Device Identifier Information for all the medical device and medical supplies listed in the Food and Drug Administration (FDA) Global Unique Device Identification Database Directory (GUDID).

- **Date of document issuance**: January 2026

- **Replacement / Revision Status**: Revision to previous version

- **Agency Identifier**: OHEI TDG 4786

- **Summary of Document**: The instructions document provides details about the use of the Device Name and Primary Device Identifier (PDI) dataset (CSV).

- **Citation to statutory provision/regulation applicable to this document**:
    - **Statute citation**: SEC. 1128G. [42 U.S.C. 1320a-7h]
    - **Rule citation**: 42 C.F.R. §403.900-14