

# Medical Device and Medical Supply Name and Primary Device Identifier Preliminary Dataset Instructions Calendar Year 2021 (Data Collection Support)

## 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. Reporting entities will begin collecting data on the “Primary Device Identifier” for medical devices and medical supplies in calendar year 2021. The Open Payments system will allow reporting of the “Primary Device Identifier” for all applicable medical devices and medical supplies beginning with the Program Year 2021 data submission in calendar year 2022. This dataset is a preliminary dataset and is provided to support data collection in the calendar year 2021.

This preliminary reference data includes medical device and medical supply name and Primary Device Identifier 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 June 30<sup>th</sup>, 2020.

An active list of devices is located on the Access GUDID website at <https://accessgudid.nlm.nih.gov/download>. The active list is a downloadable zip file containing a full list of medical device and medical supply names and Primary Device Identifier information and is refreshed monthly by the FDA. The Open Payments System will download the active list at the end of calendar year and from this zip file, the device.txt and identifiers.txt text files will be used to compile the reference dataset in the Open Payments System. NOTE: The preliminary file is generated as of June 30<sup>th</sup> 2020 GUDID active list.

## 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 Data 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.

July 2020

**O P E N P A Y M E N T S**  
CREATING PUBLIC TRANSPARENCY  
INTO INDUSTRY - PHYSICIAN  
FINANCIAL RELATIONSHIPS

**This reference dataset is not a complete list of all medical devices and medical supplies; it contains only information collected by the FDA through June 30<sup>th</sup>, 2020.**

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.

For an active list, refer to FDA GUDID Directory at <https://accessgudid.nlm.nih.gov/download/delimited>.

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 Primary Device Identifier on each general and/ or research payment or transfer of value. Primary Device Identifier information from the FDA website as of June 30<sup>th</sup>, 2020. At the end of every year CMS will update the resource file as per the FDA GUDID active list. The historical Primary Device Identifiers will be maintained in the Open Payments System; if a user reports the previous Primary Device Identifiers, the Open Payments system will recognize and validate successfully.

#### **1. Cleansing rules applied while creating CSV files:**

The following cleansing rules are applied on the medical supply name and Primary Device Identifier values against the CMS approved data source-GUDID dataset:

- Consecutive spaces reduced to one space in-between words
- Leading and trailing spaces removed
- Special characters 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.

**July 2020**

**OPEN PAYMENTS**  
CREATING PUBLIC TRANSPARENCY  
INTO INDUSTRY - PHYSICIAN  
FINANCIAL RELATIONSHIPS

- 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 Primary Device Identifier value prior to submitting the device information into the Open payments system to avoid validation error due to special characters.

## 2. 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 very large numbers of records. If the version of the Microsoft Excel is 2003 or lower, consider downloading the data file and use the import feature of Excel. In the scenario that the file is too large, it is recommended to split the file in to multiple files prior to opening into excel.
- As an alternative, a program such as Universal Viewer or Editpad Lite can be used to open the file.

## What to do 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. The reported medical devices and medical supplies will still be recognized and validated successfully in the Open Payments System. Information of new devices and supplies listed in the FDA GUDID Directory after June 30<sup>th</sup>, 2020, 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>.