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June 20, 2023

Indira Konduri
Deputy Director, Division of Surveillance Support (DSS)
Office of Regulatory Programs, Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66-1677
Silver Spring, MD 20993-0002

Re: Enhancing the FDA Global Unique Device Identification (GUDID)_ACCESS Database for Improved Patient Safety and Data Quality

Dear Deputy Director Konduri,

On behalf of Vizient, Inc., and our healthcare provider members, we urge the FDA to consider making enhancements to the FDA Global Unique Device Identification (GUDID)_Access database (hereinafter, "GUDID database"). The changes outlined below would take considerable steps to improve the utility of the GUDID database and enhance patient safety.

Vizient is the nation's largest healthcare performance improvement company. Vizient provides solutions and services that improve the delivery of high-value care by aligning cost, quality, and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers and more than 25% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Implementing effective Unique device identification (UDI) standards in healthcare is crucial for patient safety, device innovation, and post-market evaluation. Based on extensive feedback from our hospital providers, Vizient urges the FDA to consider modifications to expand the current data fields used in the GUDID database. We believe that important safety, quality, and value determinations could be advanced by transitioning several key elements of the "recommended" data fields to be included as a "required" field.

Specifically, we recommend that the fields identified below either be made "required", or for those already "required" or "conditionally required", that enhanced oversight be conducted to ensure data is being provided for those elements:

<u>Product Identification</u>:

- Device.DeviceDescription | OPTIONAL
- Device.CatalogNumber | REQUIRED
- Device.CompanyName (autopopulated) | REQUIRED

<u>Build Packaging:</u>

- Device.DeviceCount | REQUIRED
- Identifiers.containsDINumber | CONDITIONALLY REQUIRED
- Identifiers.pkgQuantity | OPTIONAL
- Identifiers.pkgType | OPTIONAL

Categorization:

- PremarketSubmission.submissionNumber | CONDITIONALLY REQUIRED
- ProductCodes.ProductCode | CONDITIONALLY REQUIRED

To illustrate the extent of some notable information gaps in the GUDID database, below are examples from the latest full GUDID database download from May 3, 2023. As of May 3, there were 3,732,408 Primary Device Identifiers (PrimaryDI) in commercial distribution and 4,844,575 total Device Identifiers (DI):

Product Identification:

- 798,082 PrimaryDI of 3,732,408 PrimaryDI in commercial distribution without a DeviceDescription (OPTIONAL)
- 1,576,535 PrimaryDI of 3,732,408 PrimaryDI in commercial distribution without a CatalogNumber (REQUIRED)

Build Packaging:

- 4,064,205 DI of 4,844,575 DI without a pkgQuantity (OPTIONAL)
- 4,219,525 DI of 4,844,575 DI without a pkgType (OPTIONAL)

Categorization:

- 2,464,462 PrimaryDI of 3,732,408 PrimaryDI in commercial distribution without a submissionNumber (CONDITIONALLY REQUIRED)
- 27,858 PrimaryDI of 3,732,408 PrimaryDI in commercial distribution without a FDAProductCode (CONDITIONALLY REQUIRED)

By elevating identified fields to be "required," or ensuring that “required”, or “conditionally required” elements are being fulfilled in the database, we believe several efficiencies and improvements may be unlocked for healthcare providers and manufacturers. Aligning these data elements will allow healthcare providers and manufacturers to more effectively conduct transactions utilizing UDI-approved data standards, such as the GS1-GTIN, HIBCC UPN, or the ICCBBA ISBT-128.

Additionally, adopting such an approach will enhance hospital and other providers’ capability to identify, compare and differentiate essential operational considerations related to product cost, quality. With additional data, hospitals and healthcare providers may be able to better respond to recalls and safety warnings, more clearly identify the safest and highest quality products, and leverage that information to improve outcomes and patient safety, while supporting value-based decision-making.

Demonstrating Vizient’s Commitment to Data Integrity

Vizient welcomes the opportunity to engage further with the FDA to support data quality enhancements and identify ways to improve the GUDID database for healthcare providers. Such beneficial collaboration could meaningfully improve the quality, comprehensiveness, and utility of the GUDID database, resulting in better patient safety and care.

In addition to leveraging Vizient expertise and experience with data and analytic tools to improve provider operations and clinical outcomes, Vizient may bring further value through data quality audits on these fields with further collaborative engagement with suppliers to close gaps in the data. In our experience in working with the GUIDID database, we have identified gaps between what data fields are required to be included and what is made available through the database on numerous products. We would be pleased to help identify such gaps and help to recognize where additional data integrity improvements could be made.

By taking such steps to enhance the availability of critical data through the GUDID database, more providers and manufacturers will adopt UDI standards, enabling better tracking of products throughout the supply chain. These improvements will in turn, support greater supply visibility, which will improve patient safety and enhance the quality of care.

Thank you for your consideration of these recommendations. We welcome the opportunity to discuss these crucial matters and further elaborate on how these recommendations could benefit the U.S. healthcare system.

Please feel free to contact me at (202) 354-2600 or Shoshana.krilow@vizientinc.com, if you have any questions or if Vizient can provide any assistance as you consider this issue.

Sincerely,

Shoshana Krilow
Senior Vice President, Public Policy & Government Relations