90 Canal St., 4th Floor, Boston, MA 02214 | +1-765-234-3463 | www.dimesociety.org

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Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852-1740

RE: Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission; Draft Guidance for Industry and Food and Drug Administration Staff

File code: FDA-2023-D-3134, Via Docket Submission

Dear FDA Review Team:

The Digital Medicine Society (DiMe) is a global non-profit dedicated to advancing the ethical, effective, equitable, and safe use of digital technologies to redefine healthcare and improve lives. DiMe appreciates the opportunity to respond to the Food and Drug Administration's *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission* draft guidance. DiMe's comment focuses exclusively on digital health technologies (DHTs).

To encourage the evolution of safer and more effective medical devices in the 510(k) program, the draft guidance proposes four best practices for manufacturers to use when selecting a predicate device. To successfully achieve the intent of this draft guidance, manufacturers will heavily rely on access to high-quality, navigable datasets. However, existing resources do not sufficiently enable manufacturers to achieve these best practices, the result of which could potentially lead to the inappropriate or incorrect selection of a predicate device.

DiMe therefore encourages FDA to: 1. redesign existing resources that manufacturers use to select a predicate device, 2. close the data gap in existing resources, and 3. develop new resources for manufacturers to rely on in achieving these four best practices. By providing DHT manufacturers and other stakeholders with access to high-quality, reliable, comprehensive data sources that enable them to optimally achieve these four best practices, the FDA will significantly improve the predictability, consistency, and transparency of the 510(k) program.

Manufacturer Responsibilities
FDA and DHT manufacturers share a common goal of providing patients with timely access to safe and effective medical devices. Timely access to safe, effective, and high-quality medical devices becomes limited if manufacturers cannot identify the most appropriate predicate device as part of the 510(k) process.

During the 510(k) process, manufacturers are responsible for:

- ***Identifying*** potential predicate device(s) to support their device's substantial equivalence to a legally marketed device.
- ***Comparing*** and ***describing*** why their device is substantially equivalent (SE) to the predicate device based on the devices' intended use, technological characteristics, and safety and effectiveness.
- ***Submitting*** a premarket notification to FDA.

As outlined in the *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission* draft guidance, manufacturers are expected to rely on existing resources to identify, compare, and describe predicate devices that are:

- Cleared using well-established methods
- Meet or exceed expected safety and performance
- Do not have unmitigated use-related or design-related safety issues
- Have not been subject to a recall due to design, manufacturing, or labeling defects

It is therefore important for manufacturers to have access to sufficient and reliable resources that enable them to confidently identify the most appropriate predicate device.

Insufficient Resources to Identify and Compare Predicate Candidates

Identifying predicate candidates

As outlined in the draft guidance, manufacturers are invited to search the Establishment Registration & Device Listing database for predicates based on the trade names, manufacturers, 510(k) numbers, and classification information of similar devices. To achieve this, manufacturers must already have a baseline understanding of the specific types of predicate device candidates they are searching for.

Instead, manufacturers should be able to conduct open-ended searches based on intended use, technological characteristics, safety, and effectiveness. By conducting searches that directly relate to the same criteria FDA uses to verify predicate device appropriateness, manufacturers can identify a greater breadth and depth of predicate device candidates.

Comparing predicate candidates

When manufacturers rely on non-comprehensive product safety datasets, they are not able to fully evaluate predicate device performance in real-world settings, safety issues, and recalls.

As featured in an April 2023 BMJ Evidence-Based Medicine report, Improving FDA postmarket adverse event reporting for medical devices, reporting to the FDA's Manufacturer and User Facility Device Experience (MAUDE) database is mandatory for certain entities, including manufacturers and healthcare facilities, and voluntary for others, such as physicians and patients. Even though the MAUDE database can

provide valuable data to inform risk–benefit assessments and support evidence-based clinical care involving medical devices, there are increasing concerns regarding the usefulness of the MAUDE database in its current form for detecting and characterizing device-related adverse events.

Unless these concerns are addressed, manufacturers face a cumbersome and challenging process to efficiently and effectively analyze and compare predicate device performance in the market.

Determining real-world use
It is important for manufacturers to know which predicate devices are, or have been, used by patients in real-world settings. These insights will enable manufacturers to: 1. more accurately compare adverse events (AE) for products that are currently on the market, to products that have been recalled, voluntarily removed from the market, or have never reached the market, in addition to, 2. better correlating market access exposure to reported AE rates.

Assessing setting-specific use
Since the FDA does not conduct widespread post-market surveillance, manufacturers face numerous challenges in identifying predicate device adverse events, defects, and malfunctions across a product's multiple settings of use. DiMe encourages increased use of Unique Device Identifiers (UDI) to better track products, respond to safety recalls, and assist in data collection. Instead of relying on manual searches of recalled device notices, FDA should consider developing a centralized repository of product recalls that include UDIs, context of use, and relevant safety data.

Calls to Action
DiMe encourages the development of improved or novel systems and processes to optimally collect, organize, and distribute critical data sources. This should include:

Redesign existing resources
It is important for the FDA to make existing resources, such as the Establishment Registration & Device Listing database, more navigable with improved access to information that enables optimal predicate device selection. Manufacturers should have the ability to conduct open-ended searches based on predicate intended use, technological characteristics, safety, and effectiveness. Existing search criteria (i.e., product trade names, manufacturers, 510(k) numbers, and classification information of similar devices) overly limit results and may not lead to optimal predicate device selection.

Close the data gap in existing resources
DiMe encourages the FDA to work with fellow government agencies to close the data gap that exists within existing resources, such as the MAUDE, Medical Device Reporting (MDR), and MedSun Reports databases. Manufacturers require access to reliable datasets to properly compare predicate devices and make informed decisions. Due to gaps in data reporting requirements, DiMe is concerned that

existing databases are not complete and do not optimally reflect predicate device safety profiles.

The agency could reduce data gaps through:

- Increased, more representative reporting of adverse events, defects, or malfunctions
- Implementation of appropriate quality controls within databases
- Proactively identifying areas of bias within datasets due to data gaps

Additionally, industry stakeholders would benefit from increased insights related to existing databases:

- *The types of adverse events, defects, or malfunctions being reported to each database*. Without a singular database to reference, manufacturers must navigate a patchwork of information where they are required to piece together insights from multiple sources. This may result in an incomplete picture of predicate product performance.
- *Who is required or invited to report adverse events, defects, and malfunctions to each database*. Further clarity is requested on whether database entries are generated only by product manufacturers, versus being supplemented by other entities such as patient-reported and health system-reported events. Detailed insights will help reduce bias and improve data interpretability.
- *Whether reporting to each database is mandatory or voluntary*. If reporting to a database is voluntary, then products with higher rates of reporting may appear to perform worse than products with lower rates of reporting. This bias may not accurately reflect a predicate's true performance.
- *The types and frequency at which unique product identifiers are reported to each database*. Consistent use of UDIs will enable manufacturers to better sort through AEs, interpret the results, and make an informed decision on predicate device candidates.

Develop new resources

If it is not feasible to redesign or improve existing FDA resources, DiMe encourages the development of new, fit-for-purpose resources that facilitate more streamlined, efficient, and comprehensive approaches to identifying, comparing, and describing predicate devices. This is particularly important if existing government resources such as the MAUDE, MDR, and MedSun Reports databases are not able to provide manufacturers with sufficient insights to achieve the four best practices in this draft guidance.

New resources may include:

- Comprehensive database of DHT predicate device candidates that is searchable by intended use, product type, product code, medical specialty, etc. This will foster alignment toward the development and distribution of a standardized, structured datasets across multiple data sources.
- Identification of DHT products that have achieved market access following a regulatory clearance.

- Encourage collection of post-market safety data with new systems for data collection reporting.

Conclusion
Identifying predicate devices is a critical step in the 510(k) submission process. Without access to complete, reliable, and easily navigable datasets, manufacturers are at risk of identifying sub-optimal predicate devices. Inaccuracies in this process could lead to unnecessary clinical evidence requirements, reduction or modification of device functionality to better align with a predicate device, delayed time to market, or reduced patient access and clinical impact.

Redesigning existing resources, closing the data gap in existing resources, and developing new resources are all opportunities for the FDA to remove unnecessary regulatory barriers, improve manufacturer clarity and consistency, and reduce product time to market.

Thank you for providing this opportunity to respond to this draft guidance. We look forward to partnering with the FDA to further develop these critical resources.

Sincerely,

Jennifer Goldsack, MChem, MA, MBA, OLY
CEO

Megan Coder, PharmD, MBA
VP, Product & Policy