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FDA Alerts Industry On GUDID Compliance

by Elizabeth Orr

Companies that the FDA believes are out of compliance with GUDID are getting letters from the agency – including some firms that should be UDI-exempt.

The US Food and Drug Administration is sending out letters to alert device manufacturers to potential problems with information in the Global Unique Device Identification Database (GUDID).

The letters specifically address an apparent mismatch between device establishment registration and listing records and UDI information loaded into GUDID, says Sarah Fitzgerald, US program manager for Emergo by UL. Fitzgerald told *Medtech Insight* that the letters began to appear the week of 6 June. The consulting firm, which also serves as an official FDA correspondent for some device companies, has already seen dozens.

Most devices needed to be listed in GUDID by the end of 2022, but exemptions exist for certain categories such as custom devices and devices intended for use only outside the US, as well as most class I devices. (For a full list of exemptions, see the sidebar.) (Also see "*Updated GUDID Data Shows Product Details For 4M Devices*" - Medtech Insight, 31 Jan, 2023.)

But Fitzgerald says the system-generated letters are being sent even to some companies with valid exemptions —possibly because the FDA's process doesn't seem to look for exemptions.

"We don't have internal insight into the FDA, but what it appears to be is that they're looking at the GUDID database, which is where a company is supposed to put all of the UDI information, and then

UDI-Exempt Devices

While most devices had to be entered into GUDID by the end of last year, some are exempt. These include:

- Class I devices that are exempt from good

the establishment registration and device listing, which is the other database that a company has to register with and saying, 'Hey, these aren't matching up,'" she says.

What should a company do if it has received one of these letters?

First, Fitzgerald says, the firm should check to see if it might fall under an exemption that the FDA failed to recognize. If that is the case, the company technically does not need to do anything – though Fitzgerald recommends that manufacturers take a minute to write a letter to the FDA explaining that they believe the product is exempt.

"It is important to evaluate and take the appropriate action, and we do recommend responding to the FDA either way because we don't want the FDA thinking that a company's potentially not in compliance," she says. "Because they can take actions. They can, for example, prioritize inspections of companies that they have concerns with that may not be in compliance, and they can even bump up their inspection types so they can bump it from a routine inspection to a for-cause inspection."

manufacturing practices

- Custom devices
- Devices intended only for export from the US
- Devices for which the FDA has established a performance standard that states an exemption to §801.20 compliance
- Most combination products with a national drug code (NDC)
- Most Class I, 510(k)-exempt devices sold over the counter that are labeled with a universal product code (UPC)

Source: Emergo by UL

Check For Data-Entry Errors

If the company finds there is a problem, the next steps depend on exactly what the problem is. If the database mismatch is caused by something like a data entry error -- for example, a misspelled address -- updating for consistency should only take about half an hour, Fitzgerald estimates. Luckily, most letters Emergo is aware of either fall under exemptions or required only this kind of quick fix.

On the other hand, some companies may learn they are genuinely out of compliance with UDI. If that is the case, the process of requesting a new UDI from an FDA-accredited organization, adding it to device labeling, and registering it in the GUDID database may take up to several months.

In a statement, the FDA confirmed that the letters are being sent.

“Industry compliance with the UDI requirements and GUDID are essential to achieving the potential benefits of UDI, such as reducing medical errors and supporting a more secure global device supply chain,” spokesperson Audra Harrison wrote. “The FDA recently sent letters to device manufacturers to remind firms to review their GUDID submissions to ensure all applicable device records are submitted to the GUDID.”