Device, digital health firms oppose HHS' proposed 510(k) exemptions

Posted 23 March 2021 | By Michael Mezher

Medical device and digital health companies have largely come out in opposition to a proposal from the Department of Health and Human Services (HHS) to permanently exempt 84 types of medical devices from premarket notification (510(k) requirements.

The proposal was made in the final days of the Trump administration and was pushed through without consulting the US Food and Drug Administration (FDA), the agency that would typically issue such a notice. All the devices included in the proposal, which include 83 Class II devices and one unclassified device, were temporarily exempted from premarket review requirements during the COVID-19 public health emergency (PHE). (RELATED: *HHS pushes through last-minute policies impacting FDA*, *Regulatory Focus* 12 January 2021).

While the timing of the proposal and the methodology employed to justify exempting the devices from 510(k) requirements have come under fire, it is not uncommon for FDA to exempt devices from 510(k) requirements and the agency is tasked with reviewing whether Class I and II devices should be exempted every five years under the *21st Century Cures Act*.

The proposal is currently on hold subject to President Joe Biden's regulatory freeze. (RELATED: *Biden's day one regulatory freeze*, *Regulatory Focus* 21 January 2021).

Many of the industry comments on the proposal were critical and either called for a return to status quo following the pandemic or for FDA to find other ways to ease the regulatory burden for the devices listed in the notice.

"It is important for existing or more appropriately tailored regulatory pathways to be reinstated following this emergency period. This is necessary since HHS 86 FR 4088 proposes stripping Class II devices on the

list from premarket notification requirements without implementing other controls to protect public health and safety," the Digital Therapeutics Alliance (DTA) wrote. The alliance also called HHS' reliance on data from FDA's Manufacturer and User Facility Device Experience (MAUDE) database "flawed and incomplete."

"MAUDE is a collection of individual reports from manufacturers, importers, and medical device users. Since the database has no mechanism to identify or correct missing, erroneous, or incomplete information, its value should not be elevated beyond a reference tool," DTA wrote.

Instead of exempting the devices listed in the proposed rule, DTA calls on HHS and FDA to work with industry to develop "appropriate and necessary pathways for [digital therapeutic] DTx product review and access in the post-PHE period" and to ensure continuity of access to digital therapeutics marketed under the agency's pandemic enforcement policy.

The Medical Imaging and Technology Alliance (MITA) raised similar issues with the methodology used to determine which devices to exempt and said the notice has created confusion among manufacturers. MITA also took the opportunity to champion the existing 510(k) program and its substantial equivalence pathway.

In its comments, Baxter Healthcare argued against the proposal to exempt infusion safety management software used in current generation infusion pumps from 510(k) requirements and instead called on FDA to consider reducing the administrative review burden for infusion pumps by reviewing infusion safety management software under the infusion pump 510(k).

Otsuka, a developer of digital therapeutics, also pushed back against exempting the devices from 510(k) requirements based on a review of MAUDE data, calling the proposal "premature and insufficiently tailored to the complexities at play."

"We respectfully maintain that the enactment of permanent exemptions from premarket requirements that have long been deemed necessary to provide a reasonable assurance of safety and effectiveness should be undertaken only after more extensive review of available information, and careful consideration of the differences between the diverse device types addressed in the subject notice," Otsuka wrote, noting that FDA is "well suited" to conduct such an analysis, as the agency has done in exempting numerous other devices from 510(k) requirements in the past.

Otsuka points out that it takes FDA only about 20 hours on average to review a 510(k) submission compared to 1,200 hours for a premarket approval (PMA) application and that while there are costs associated with submitting a 510(k), most of the costs "would need to be borne by manufacturers who aim to bring a genuine therapy to market regardless of whether the device type is exempt."

Roche Diagnostics, on the other hand, strongly backed the proposal to lift premarket notification requirements for four types of digital pathology devices, whole slide imaging systems, digital pathology displays, automated digital image manual interpretation microscopes and digital pathology image viewing and management software.

"As healthcare advances and the risk profiles associated with existing, established technologies are well understood, it is important that health authorities revisit approaches to the regulation of devices to ensure that safety and effectiveness is balanced with speed of innovation," Roche wrote, pointing out that

the devices will still be held to other regulatory requirements, including general and special controls and quality system requirements.

The Mayo Clinic also voiced support for exempting three of the same digital pathology devices from 510(k) notification requirements, all except for automated digital image manual interpretation microscopes. However, the hospital cautioned that any permanent exemptions "should be accompanied by continuous evaluation of the risk presented by digital slide scanners as more data is gathered."

Regulations.gov