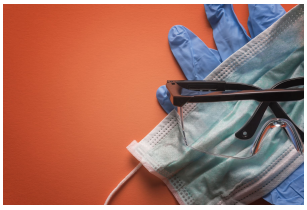

FDA Permanently Exempts Seven Class I Gloves from 510(k) Premarket Notification Process

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Update: As of April 16, 2021, it appears the FDA may be reversing course with respect to its prior exemption of Class I gloves from the premarket notification process. Read our analysis of the FDA's evolving position.

The Department of Health and Human Services (HHS) made the Food and Drug Administration's (FDA) temporary exemption from the 510(k) premarket notification process permanent for seven Class I medical devices. HHS is also considering whether to extend this permanent exemption to an additional 84 class II medical devices, subject to approval by the Biden administration. On January 15, 2021, HHS published its "Notice about making permanent regulatory flexibilities during COVID-19 related to certain medical devices" (Federal Register Doc. #2021-00787). Through the Notice, HHS identified seven class I devices—all medical gloves—as exempt from the 510(k) premarket notification requirements. The newly exempt gloves include:

Device Description
Powder-Free Polychloroprene Patient Examination Glove
Patient Examination Glove, Specialty
Radiation Examination Glove, Specialty
Powder-Free Non-Natural Rubber Latex Surgeon's Gloves
Powder-Free Guayle Rubber Examination Glove
Latex Patient Examination Glove
Vinyl Patient Examination Glove

In March 2020, to address the personal protective equipment (PPE) shortfall caused by COVID-19, the FDA suspended the 510(k) premarket notification requirements for a variety of gloves, including the categories listed above. In its "Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease

(COVID-19) Public Health Emergency," issued in March 2020, the FDA effectively waived a variety of the compliance and quality regulations related to surgeon's and patient examination gloves, including 510(k) premarket notification. HHS compared adverse effects reported through the FDA's MAUDE system prior to March 2020 and after issuance of the Enforcement Policy. Based on this information, HHS determined that because a minimal number of adverse events related to the seven product codes listed above were reported since issuance of the Enforcement Policy, the 510(k) premarket notification was no longer necessary for these devices.

During the pendency of the public health emergency related to COVID-19, the Enforcement Policy waived other regulatory requirements for the examination gloves—e.g., registration and listing and reports of corrections and removals. However, it is important to note that once the public health emergency is lifted, these regulatory requirements are unaffected by HHS's January 15 Notice. Therefore, manufacturers and those responsible parties in the supply chain will need to be on high alert and ready to ensure a return to compliance with all applicable regulations.

The Notice also identified an additional 84 class II devices that HHS proposed to exempt from the 510(k) premarket notification requirements. Some of the class II devices include additional PPE such as Pediatric/Child Facemask (OXZ); N95 Respirator With Antimicrobial/Antiviral Agent For Use By The General Public In Public Health Medical Emergencies (ORW); N95 Respirator With Antimicrobial/Antiviral Agent (OKC); Surgical Mask With Antimicrobial/Antiviral Agent (OUK); and Gown, Isolation, Surgical (FYC). Under the Notice, the exemption could have gone into effect by the end of March 2021. However, on January 20, 2021, President Biden's Chief of Staff issued the memorandum "Regulatory Freeze Pending Review." The memorandum ultimately prevents HHS's Notice from going into effect with respect to the 84 class II devices unless approved by the new administration, which is unlikely.

If you have any questions about FDA medical device compliance or the new medical device 510(k) exemptions, please contact Maureen Bickley (513-651-6107; mbickley@fbtlaw.com) or Kaitlyn Hawkins-Yokley (513-651-6972; khawkinsyokley@fbtlaw.com).

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