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# FDA Reverses HHS Exemption of Class I and Class II Medical Devices from Section 510(k)

## Premarket Notification Again Required for Patient and Surgeon's Examination Gloves and Dozens of Class II Devices Proposed for Exemption by Former HHS Secretary

On April 16, 2021, the Food and Drug Administration ("FDA" or "the Agency") took action to reverse a last-minute Federal Register notice published by the outgoing Trump Administration Secretary of Health and Human Services ("HHS") on January 15, 2021 (the "January 15 HHS Notice"). HHS had sought to exempt over 90 medical device types from the premarket notification requirements under Section 510(k) of the Federal Food, Drug, and Cosmetic Act. FDA has overturned the January 15 HHS Notice – on which FDA apparently was not consulted – based on FDA's determination that HHS's proposed 510(k) exemptions, and the bases for them, were flawed. FDA's decision is reflected in two separate Federal Register notices: one reversing HHS's decision to exempt certain Class I reserved gloves, and another reversing HHS's proposal to exempt 83 Class II devices and one unclassified device. As these notices explain, FDA and HHS reexamined the January 15 HHS Notice after FDA's Center for Devices and Radiological Health identified several flaws in the Notice and received dozens of inquiries about potential errors and ambiguities, as well as comments opposed to 510(k) exemptions for the Class I gloves announced in the Notice.

### JANUARY 15 HHS NOTICE RECONSIDERED BY FDA AND HHS

The January 15 HHS Notice immediately exempted seven types of Class I reserved criteria surgeon's and patient examination gloves from FDA's premarket notification or "Section 510(k)" requirements. Generally, 510(k) clearance is not required for a Class I device. However, there are two exceptions or "reserved criteria" under which FDA requires 510(k)

clearance for Class I devices: (1) Class I devices intended for a use that is of substantial importance in preventing impairment of human health; and (2) any Class I device that presents a potential unreasonable risk of illness or injury.

The January 15 HHS Notice also proposed to exempt 83 Class II devices and one unclassified device from 510(k) review. Class II devices generally are subject to Section 510(k) premarket notification requirements; however, if FDA determines that a Section 510(k) report is not necessary to assure the safety and effectiveness of the device, FDA is authorized to publish a notice of intent to exempt a Class II device from Section 510(k) in the Federal Register.

As explained in the two April 16 Federal Register notices, in the January 15 HHS Notice, HHS did not base its decision to exempt the Class I reserved gloves on the reserved criteria (i.e., there was no consideration of whether the exempted devices are not intended for a use that is of substantial importance in preventing impairment of human health, or do not present a potential unreasonable risk of illness or injury). Nor did HHS base its proposal to exempt dozens of Class II devices using factors outlined in FDA guidance. Further, HHS apparently did not consult or even provide advance notification to FDA regarding these important regulatory decisions. Citing President Trump's Executive Order No. 13924, which instructed the heads of all agencies to "review any regulatory standards that they have temporarily rescinded, suspended, modified, or waived during the public health emergency," in order to "determine which, if any, would promote economic recovery if made permanent," HHS undertook an evaluation to determine whether FDA's temporary waiver of section 510(k) premarket notification requirements for some devices during the COVID-19 Public Health Emergency ("PHE") should be made permanent. HHS based its decisions on an analysis of adverse event records for devices in FDA's MAUDE database from November 1, 2010 to November 30, 2020. HHS reviewed the number of the reports from November 1, 2010 to the beginning of the PHE when FDA issued the enforcement policy guidances, and for the time period from the beginning of the PHE to November 30, 2020. HHS implemented or proposed exemptions from 510(k) requirements for relevant devices with no or low numbers of adverse event reports in MAUDE during the time period since the beginning of the PHE.

## APRIL 16 NOTICE REINSTATES 510(K) CLEARANCE REQUIREMENTS FOR SEVEN TYPES OF SURGEON'S AND PATIENT EXAMINATION GLOVES

With respect to the exemption of the Class I reserved criteria gloves, HHS and FDA concluded the determinations in the January 15 HHS Notice lack adequate legal and scientific support, and that the January 15 HHS Notice is otherwise flawed, because HHS did not discuss the reserved criteria in the statute, explain how HHS came to determine the gloves no longer meet the reserved criteria, or cite the statutory standard. Moreover, the standard applied, "reasonable assurance of safety and effectiveness," did not in fact consider the gloves' effectiveness. FDA and HHS concluded that all types of patient examination and surgeon's gloves (other than a finger cot) continue to meet the reserved criteria because they are intended for uses which are of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury. Surgeon's gloves and patient examination gloves are generally intended to prevent contamination and the spread of pathogens and can be the key barrier that protects against the spread of infection between individuals. They can also protect against occupational exposure to chemotherapy drugs, which have potential mutagenic, carcinogenic, and teratogenic effects. Because these gloves play an important role in preventing risks to the public, FDA continues to believe premarket notification is necessary to provide reasonable assurance of their safety and effectiveness.

## APRIL 16 NOTICE RESCINDS PROPOSAL TO EXEMPT 84 DEVICE TYPES FROM 510(K) CLEARANCE REQUIREMENT

HHS and FDA determined that the proposed Class II and unclassified device exemptions in the January 15 HHS Notice were also published without adequate scientific support, and that the Notice contains errors and ambiguities and is otherwise flawed. FDA explained that, to exempt a device from 510(k) clearance under the statutory standard, HHS was

required to determine that a 510(k) submission is no longer necessary to assure the safety or effectiveness of the device. HHS failed to consider both safety and effectiveness, relying solely on its tally of adverse event reports.

## JANUARY 15 HHS NOTICE INAPPROPRIATELY RELIED ON MAUDE DATA

In both April 16 Federal Register Notices, FDA and HHS were critical of HHS' reliance on adverse events reports alone to support the Class I exemptions and Class II proposed exemptions in several respects:

- Adverse event reports in MAUDE have limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. The incidence or prevalence of an event cannot be determined solely from adverse event reports for many reasons.
- Adverse event reports alone are not adequate for assessing safety, let alone for determining a device to be exempt from 510(k). A safety assessment should also consider FDA's experience in reviewing 510(k)s for these devices. The products' recall history is another important part of the risk analysis.
- Adverse event data may provide little or no information about effectiveness.
- Adverse events may be underreported, and a low number of MAUDE reports may reflect the low number of marketed devices, and not necessarily the risk of injury.
- Adverse event reporting has been more difficult during the PHE and, thus, underreporting may have been greater than usual.

## FDA'S ENFORCEMENT POLICY DURING THE PUBLIC HEALTH EMERGENCY

In explaining its reversals, FDA and HHS also provided important context for the issuance of guidance documents setting forth enforcement policies during the COVID-19 PHE intended to help expand the availability of certain devices:

- Enforcement policies were issued specifically in response to, and for the duration of, the COVID-19 PHE, the most sweeping and substantial PHE to occur in over a century.
- Enforcement policies were limited in scope and fundamentally different from a determination that the subject devices no longer meet the reserved criteria or otherwise no longer require a 510(k).
- Enforcement policies communicate FDA's nonbinding views about how it should allocate its enforcement resources based on current facts and circumstances, do not alter the legal obligation to comply with the relevant requirements, and do not preclude FDA from taking action to enforce those requirements where appropriate.

## INCREASED SURVEILLANCE OF THE SEVEN TYPES OF GLOVES SUBJECT TO THE JANUARY 15, 2021 NOTICE

FDA also announced that it intends to increase its surveillance of the seven types of gloves subject to the January 15 HHS Notice. Such increased surveillance may include a labeling review and a physical examination to assess for physical defects. Because FDA expects that most such gloves are imported, FDA's focus will be on products at the time of importation.

## OTHER HHS ACTIONS DURING THE TRUMP ADMINISTRATION TAKEN WITHOUT FDA CONSULTATION

FDA and HHS' action to reverse HHS' last minute 510(k) exemptions may portend similar actions in the coming weeks or months, particularly where HHS appears to have acted without consulting FDA. Another HHS decision in 2020 that we are monitoring for potential action is an August 19, 2020 HHS announcement that rescinded all FDA guidance, compliance manuals, website statements, and other informal issuances concerning FDA premarket review of laboratory developed tests ("LDTs"). The announcement applied to all LDTs—including COVID-19 LDTs—and stated that FDA may

not require premarket review for these tests absent a notice-and-comment rulemaking process. That announcement is no longer posted on HHS' website.

## ACTIONS TO UNDERTAKE

We encourage device firms to review the January 15 HHS Notice to determine whether their devices were affected by the proposed exemptions, and ensure they are in compliance with applicable premarket requirements or enforcement discretion policies in existence prior to the January 15 HHS Notice. Manufacturers and initial importers of Class I "reserved criteria" gloves that have introduced, or offered them for sale, in interstate commerce for the first time and have not filed a premarket notification must obtain 510(k) clearance from FDA (or comply with the parameters of enforcement discretion policies as long as they remain in effect), as the exemptions have been reversed. Manufacturers of one or more of the 83 Class II devices and 1 unclassified device shall, as a result of the April 16, 2021 withdrawal of proposed exemption to premarket notification, continue to submit 510(k)s in accordance with the Act and FDA regulations, or conform to applicable enforcement discretion guidances.

Please feel free to reach out with any questions or concerns, as we remain ready to assist in any way, or answer any questions that may arise.