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FDA Publishes List of Class I Devices Exempted From 510(k) Process

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As previously reported, Congress passed and then-President Obama signed the 21st Century Cures Act last December to implement a number of FDA reforms. Among the reforms affecting medical devices was a requirement for the FDA to publish a notice in the Federal Register – within 120 days for Class I devices and within 90 days for Class II devices –identifying devices that no longer require clearance under Section 510(k). The FDA previously published the list of Class II devices and has now published the list of Class I devices.

Unlike the list for Class II devices, which required a 60-day notice and comment period before it could be finalized, the Class I exemptions are effective immediately.

The notice cautions that an exemption from the 510(k) process "does not mean that the device is exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation." The FDA states that its initial determination that premarket notification is unnecessary to provide a reasonable assurance of safety and effectiveness for devices listed in the notice is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements, provide.

The Class I list includes 70 devices, most of which are from 21 CFR Part 862, which governs clinical chemistry and clinical toxicology devices.

The list also includes devices from 21 CFR Parts 864 (Hematology and Pathology), 866 (Immunology and Microbiology), 872 (Dental), 876 (Gastroenterology-Urology), 878 (General and Plastic Surgery), 880 (General Hospital and Personal Use), 882 (Neurological), 884 (Obstetrical and Gynecological), and 886 (Opthalmic).

Medical device firms will want to consider reviewing the list to determine if any of their current or proposed products are now exempt. The FDA is required to update these lists every five years.

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