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HHS Publishes Notice Exempting Devices from Premarket Review in Final Days of Trump Administration

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Food, Drugs, and Devices

On January 15, the final Friday of the Trump administration, the Department of Health and Human Services ("HHS") published in the Federal Register a notice permanently exempting or proposing to exempt 101 medical devices that previously required a premarket clearance under section 510(k) of the Food, Drug & Cosmetic Act ("FDCA"). Under the notice, seven class I medical devices were immediately, permanently exempted from the 510(k) premarket review requirement, and eighty-three class II devices and one unclassified device were proposed to be permanently exempted from such requirement. The notice is not affected by President Biden's inauguration-day regulatory freeze that otherwise prevents Trump-era rules from going into effect after the transition because (1) the exemption of class 1 devices was effective prior to January 20, 2021, and (2) the proposal to exempt class II and unclassified devices was only a proposal, and further action is still required from FDA.

The notice explains that devices were selected after a review of medical device reports ("MDRs") submitted to the Manufacturer and User Facility Device Experience ("MAUDE") database between November 1, 2010 and November 30, 2020 for 184 device types. These device types are subject to one of thirteen FDA enforcement policies temporarily waiving the 510(k) premarket notification requirement in response to the COVID-19 public health emergency ("PHE"). The MDR review considered MDRs submitted prior to and following the beginning of the PHE, when the enforcement policies were in effect.

The MDR review was conducted consistent with (1) President Trump's Executive Order No. 13924, instructing agency heads to review "regulatory standards" that were "temporarily rescinded, suspended, modified, or waived during the public health emergency," to determine if any of them, if made permanent, would benefit the economic recovery[1] and (2) Congress's instruction in the 21st Century Cures Act that FDA consider whether to exempt class I and II devices from the section 510(k) requirement "at least once every 5 years."[2] In determining that

1 Executive Order 13924 of May 19, 2020, Regulatory Relief to Support Economic Recovery, 85 Fed. Reg. 31353 (May 22, 2020).

2 See FDCA § 510(l)(1) ("Not later than 120 calendar days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance

the costs associated with 510(k) clearance and premarket approval requirements constitute barriers to entering the U.S. market, HHS stated that in the absence of "corresponding safety and efficacy benefits for Americans, those barriers are unjustified."

Based on the MDR review, HHS determined that 510(k) premarket notifications are not necessary for seven types of gloves for which there were either zero MDRs or a "de minimis" number of adverse events in MAUDE following FDA's waiver of the premarket notification requirement in the enforcement policies (see Table 1). Additionally, HHS determined that 510(k) premarket notifications were not necessary for eighty-three class II devices and one unclassified device for which there were either zero MDRs, or a "lack of [death]-related adverse event reports"[3] in MAUDE following FDA's waiver of the 510(k) requirement in the enforcement policies. These devices, proposed to be exempt from the premarket notification requirement, are listed in Table 2 at the end of this alert.

Notably, some device types were established relatively recently, e.g., image acquisition and/or optimization guided by artificial intelligence (21 CFR 892.2100, product code QJU), for which *de novo* classification occurred Feb. 7, 2020. Thus, the period for submission of MDRs would have been relatively short, particularly prior to the beginning of the PHE, raising questions about the value of using MDR data to inform exemptions.

HHS is accepting comments on the proposal to exempt the class II and unclassified devices for 60 days. It is unclear, however, whether the new Biden administration will finalize some, all, or none of the proposal. At a minimum, we would expect the new administration to closely examine the proposed exemptions for those devices with limited postmarket data.

Table 1: Class I Devices Immediately Exempt from 510(k) Notification Requirement

Device Description	Device Class	Product Code	Section in 21 CFR
Powder-Free Polychloroprene Patient Examination Glove	I	OPC	880.6250
Patient Examination Glove, Specialty	I	LZC	880.6250
Radiation Attenuating Medical Glove	I	OPH	880.6250

of safety and effectiveness."); id. § 510(m)(1)(A) ("The Secretary shall not later than 90 days after the date of the enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate (i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and (ii) provide for a period of not less than 60 calendar days for public comment beginning on the date of the publication of such notice....")

3 The notice states "lack of non-death-related adverse event reports," but this appears to be a typo, as the proposed exempted devices lack death-related adverse event reports, but do have other adverse event reports.

Powder-Free Non-Natural Rubber Latex Surgeon's Gloves	I	OPA	878.4460
Powder-Free Guayle Rubber Examination Glove	I	OIG	880.6250
Latex Patient Examination Glove	I	LYY	880.6250
Vinyl Patient Examination Glove	I	LYZ	880.6250

Table 2: Class II Devices and Unclassified Devices Proposed Exempt from 510(k) Requirement

Device Description	Device Class	Product Code	Section in 21 CFR
Ventilator, Continuous, Minimal Ventilatory Support, Home Use	II	NQY	868.5895
Airway Monitoring System	II	OQU	868.5730
Impedance Measuring Device Utilizing Oscillation Techniques	II	PNV	868.1840
Gauge, Pressure, Coronary, Cardiopulmonary Bypass	II	DXS	870.4310
Valve, Pressure Relief, Cardiopulmonary Bypass	II	MNJ	870.4400
Oximeter, Tissue Saturation, Reprocessed	II	NMD	870.2700
Multivariate Vital Signs Index	II	PLB	870.2300
Electrocardiograph Software For Over-The-Counter Use	II	QDA	870.2345
Sterilizer, Dry Heat	II	KMH	880.6870
Check Valve, Retrograde Flow (In-Line)	II	MJF	880.5440
Intravascular Administration Set, Automated Air Removal System	II	OKL	880.5445

Neuraxial Administration Set—Intrathecal Delivery	II	PYR	880.5440
High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Liquid	II	PSW	892.1570
Pediatric/Child Facemask	II	OXZ	878.4040
Normalizing Quantitative Electroencephalograph Software	II	OLU	882.1400
Computerized Cognitive Assessment Aid	II	PKQ	882.1470
Physiological Signal Based Seizure Monitoring System	II	POS	882.1580
Computerized Behavioral Therapy Device For Psychiatric Disorders	II	PWE	882.5801
Monitor, Phonocardiographic, Fetal	II	HFP	884.2640
Monitor, Cardiac, Fetal	II	KXN	884.2600
Digital Pathology Display	II	PZZ	864.3700
Digital Pathology Image Viewing and Management Software	II	QKQ	864.3700
System, Imaging, Holography, Acoustic	II	NCS	892.1550
Lung Computed Tomography System, Computer-Aided Detection	II	OEB	892.2050
Chest X-Ray Computer Aided Detection	II	OMJ	892.2050
Computer-Assisted Diagnostic Software For Lesions Suspicious For Cancer	II	POK	892.2060
Radiological Computer-Assisted Triage and Notification Software	II	QAS	892.2080

Radiological Computer Assisted Detection/Diagnosis Software For Fracture	II	QBS	892.2090
Radiological Computer Assisted Detection/Diagnosis Software For Lesions Suspicious For Cancer	II	QDQ	892.2090
Radiological Computer-Assisted Prioritization Software For Lesions	II	QFM	892.2080
X-Ray Angiographic Imaging Based Coronary Vascular Simulation Software Device	II	QHA	892.1600
Automated Radiological Image Processing Software	II	QIH	892.2050
Image Acquisition And/Or Optimization Guided By Artificial Intelligence	II	QJU	892.2100
Apparatus, Vestibular Analysis	Unclassified.	LXV	N/A
Meter, Peak Flow, Spirometry	II	BZH	868.1860
Oximeter, Reprocessed	II	NLF	870.2700
Stethoscope, Electronic	II	DQD	870.1875
Defoamer, Cardiopulmonary Bypass	II	DTP	870.4230
Filter, Blood, Cardiotomy Suction Line, Cardiopulmonary Bypass	II	JOD	870.4270
Detector, Bubble, Cardiopulmonary Bypass	II	KRL	870.4205
Cpb Check Valve, Retrograde Flow, In-Line	II	MJJ	870.4400
Sterilizer, Ethylene-Oxide Gas	II	FLF	880.6860
Cabinet, Ethylene-Oxide Gas Aerator	II	FLI	880.6100
Purifier, Air, Ultraviolet, Medical	II	FRA	8860.6500

Cleaner, Air, Medical Recirculating	II	FRF	880.5045
Controller, Infusion, Intravascular, Electronic	II	LDR	880.5725
Cleaners, Medical Devices	II	MDZ	880.6992
Percutaneous, Implanted, Long-Term Intravascular Catheter Accessory For Catheter Position	II	OMF	880.5970
N95 Respirator With Antimicrobial/Antiviral Agent For Use By The General Public In Public Health Medical Emergencies	II	ORW	880.6260
Two Or More Sterilant Sterilizer	II	PJJ	880.6860
High Level Disinfection Reprocessing Instrument For Ultrasonic Transducers, Mist	II	OUJ	892.1570
Surgical Mask With Antimicrobial/Antiviral Agent	II	OUK	878.4040
Cerebral Oximeter	II	QEM	870.2700
Device, Sleep Assessment	II	LEL	882.5050
Standard Polysomnograph With Electroenchephalograph	II	OLV	882.1400
Source Localization Software For Electroencephalograph Or Magnetoencephalograph	II	OLX	882.1400
Automatic Event Detection Software For Polysomnograph With Electroencephalograph	II	OLZ	882.1400
Amplitude-Integrated Electroencephalograph	II	OMA	882.1400
Automatic Event Detection Software For Full-Montage Electroencephalograph	II	OMB	882.1400
Burst Suppression Detection Software For Electroencephalograph	II	ORT	882.1400

Transducer, Ultrasonic, Obstetric	II	HGL	884.2960
Tonometer, Ac-Powered	II	HKX	886.1930
Tonometer, Manual	II	HKY	886.1930
Automated Digital Image Manual Interpretation Microscope	II	OEO	864.1860
Analyzer, Medical Image	II	MYN	892.2070
C-Arm Fluoroscopic X-Ray System	II	RCC	892.1650
Cannula, Arterial, Cardiopulmonary Bypass (Cpb), Embolism Protection	II	NCP	870.4210
Respirator, N95, For Use By The General Public In Public Health Medical Emergencies	II	NZJ	880.6260
Sterilizer Automated Loading System	II	PEC	880.6880
Infusion Safety Management Software	II	PHC	880.5725
Gown, Isolation, Surgical	II	FYC	878.4040
Whole Slide Imaging System	II	PSY	864.3700
Oxygenator, Long Term Support Greater Than 6 Hours	II	BZG	868.1840
Subcutaneous Implanted Apheresis Port	II	QAV	868.5454
Non-Coring (Huber) Needle	II	BYS	870.4100
Hood, Surgical	II	MAJ	868.5120
N95 Respirator With Antimicrobial/Antiviral Agent	II	OKC	880.5970
Monitor, Uterine Contraction, External (For Use In Clinic)	II	PTI	880.5570

Coil, Magnetic Resonance, Specialty	II	PWH	880.5440
Oxygenator, Long Term Support Greater Than 6 Hours	II	FXY	878.4040
Transmitters And Receivers, Electrocardiograph, Telephone	II	ONT	878.4040
Extracorporeal System For Long-Term Respiratory/Cardiopulmonary Failure	II	OMC	882.1400
Implanted Subcutaneous Securement Catheter	II	MOS	892.1000
Subcutaneous Implanted Apheresis Port	II	QHY	892.1650

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