Cooley

FCC Grants Equipment Authorization Waiver to GE Healthcare for Medical Devices

May 18, 2020

In light of issues raised by the COVID-19 emergency, the Federal Communications Commission **has waived its rules** to permit GE Healthcare to market, import and sell medical devices before those devices have completed its equipment authorization process. The waiver covers both new products and existing devices that may have to be modified to replace components that are not available during the emergency and is limited to devices that are used in medical facilities. This waiver is unusual, and it suggests that the FCC would provide similar relief to other medical device manufacturers.

GE Healthcare requested the waiver for two reasons: (1) Supply chain disruptions may affect its ability to obtain components for its existing products, which would require substitution of new components that might require new testing and approval from the FCC and (2) as a result of the COVID-19 pandemic, the capacity of test labs and telecommunications certification bodies (which prepare, file and review applications for equipment authorization) may be overwhelmed, leading to delays in obtaining authorizations. The FCC agreed that, given the demand for medical devices resulting from the pandemic, these concerns justified allowing GE Healthcare to sell particular types of devices without completing the authorization process.

The waiver will remain in effect for 18 months. It covers any devices GE Healthcare markets to healthcare providers for use at healthcare facilities, including patient monitors, telemetry transmitters and antenna infrastructure; diagnostic testing devices; and mobile radiology and portable X-ray devices. The waiver applies to devices that operate under multiple parts of the FCC's rules – the rules for unlicensed devices, for medical devices in general, for wireless telemetry and for medical devices that require FCC licenses. GE Healthcare's ability to market, import and sell devices is subject to the following conditions:

- The devices must be tested by GE Healthcare or a third party for compliance with the substantive requirements of the FCC's rules
- The devices can be operated only at the direction of authorized health care providers at healthcare facilities, including temporary facilities used during the COVID-19 emergency. Devices intended for home use are not covered by the waiver
- GE Healthcare must apply for FCC authorization for any individual device no more than 180 days after it begins marketing the device
- Every device covered by the waiver must include a special warning label and comply with all other FCC labeling requirements
- GE Healthcare must maintain a list of all covered devices that are imported and marketed and of the healthcare facilities to which they are distributed
- Any device that will not be authorized by the FCC by the end of the waiver period must be disabled or retrieved by GE Healthcare before the waiver expires

It is unusual for the FCC to grant relief from its equipment authorization process. While the waiver contains significant safeguards to prevent potential harms, including testing before the devices can be marketed, requiring special labels and an obligation for GE Healthcare to retrieve or disable any devices that are not ultimately approved for use, it still is a significant step. It is likely that the FCC would grant similar waivers to medical device manufacturers that would benefit from this kind of relief.

This content is provided for general informational purposes only, and your access or use of the content does not create an

attorney-client relationship between you or your organization and Cooley LLP, Cooley (UK) LLP, or any other affiliated practice or entity (collectively referred to as "Cooley"). By accessing this content, you agree that the information provided does not constitute legal or other professional advice. This content is not a substitute for obtaining legal advice from a qualified attorney licensed in your jurisdiction, and you should not act or refrain from acting based on this content. This content may be changed without notice. It is not guaranteed to be complete, correct or up to date, and it may not reflect the most current legal developments. Prior results do not guarantee a similar outcome. Do not send any confidential information to Cooley, as we do not have any duty to keep any information you provide to us confidential. When advising companies, our attorney-client relationship is with the company, not with any individual. This content may have been generated with the assistance of artificial intelligence (AI) in accordance with our AI Principles, may be considered Attorney Advertising and is subject to our **legal notices**.

Key Contacts

Christy Burrow Washington, DC	cburrow@cooley.com +1 202 776 2687
J.G. Harrington Washington, DC	jgharrington@cooley.com +1 202 776 2818
Robert M. McDowell Washington, DC	rmcdowell@cooley.com +1 202 842 7862

This information is a general description of the law; it is not intended to provide specific legal advice nor is it intended to create an attorney-client relationship with Cooley LLP. Before taking any action on this information you should seek professional counsel.

Copyright © 2023 Cooley LLP, 3175 Hanover Street, Palo Alto, CA 94304; Cooley (UK) LLP, 22 Bishopsgate, London, UK EC2N 4BQ. Permission is granted to make and redistribute, without charge, copies of this entire document provided that such copies are complete and unaltered and identify Cooley LLP as the author. All other rights reserved.