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FCC Grants Equipment Authorization Waiver to GE Healthcare for Medical Devices

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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.

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