WILMERHALE

FCC Releases NPRM and NOI on Spectrum Rules for Medical Devices

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On July 18, 2006, the Federal Communications Commission released a Notice of Proposed Rulemaking and Notice of Inquiry into the development and use of a variety of new medical devices that rely on radio communication for their functionality. This proceeding is intended to build upon the Medical Implant Communication Service (MICS) that the Commission established in 1999.

MedRadio

The Commission has proposed to allocate two megahertz of new spectrum to establish a Medical Device Radiocommunication Service (MedRadio). Under this proposal, the existing MICS rules would generally apply, but certain MedRadio devices meeting ultra-low power and other technical requirements would be exempt from the MICS "listen-before-talk" (LBT) frequency monitoring restriction. This exemption would permit MedRadio devices to be designed with a smaller size, reduced power consumption, simplified circuitry and lower cost. Furthermore, the FCC proposal would allow MedRadio devices to include a non-implanted, "body-worn" transmitter component. The Commission seeks comment on these proposed rules and several related issues, including the possibility of imposing tighter bandwidth and power constraints on MedRadio devices, and a suggested definition for "body-worn" transmitters.

Notice of Inquiry

The Commission also issued a related, wide-ranging notice of inquiry into any new technologies that use radio communication to provide patient care and rehabilitation. In doing so, the Commission hopes to develop a complete record as a basis for possible further rule changes. The Commission is seeking comment on issues such as the selection of the appropriate frequency bands for transmission through body tissue, interference between multiple devices, harmonization with international practices, any existing or emerging industry standards for medical radio devices, and the relative merits of licensed vs. unlicensed approaches for spectrum allocation. The Commission also seeks comment on its joint efforts with the Food and Drug Administration, including whether such efforts should expand into areas of pre-deployment device design, and whether the Commission's rules should cross-reference related FDA rules.

Comments

The FCC's new medical device rules will affect the design, operation and sale of such devices within the United States, and will be in effect over the long term. Accordingly, this proceeding presents an important opportunity for companies hoping to design devices that might fall within the MICS or proposed new MedRadio definitions—or those producing even newer generations of medical devices—to help shape the FCC's rules and thus the opportunities for device design in the foreseeable future. Comments are due by October 31, 2006. Reply comments are due by December 4, 2006.

For more information on this or other wireless technology matters, please contact the authors listed above.