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FCC Allocates More Spectrum to Wireless Medical Devices and Proposes Even More Spectrum for Implanted Neuromuscular Stimulators

The Federal Communications Commission ("FCC") recently released an Order allocating 2 MHz of new spectrum for advanced wireless implanted devices, which may enable the certification of new devices. The FCC also seeks comment on a proposal to allocate up to 20 MHz of spectrum for implanted neuromuscular micro stimulators. Both items are described in greater detail below.

Wireless Medical Devices Report & Order

The FCC approved new rules to provide additional spectrum for wireless medical devices, such as blood glucose monitors, implanted vagus nerve stimulators, and deep brain stimulators. Current rules accommodate wireless implanted medical devices for a variety of diagnostic and therapeutic functions. Advances in both implanted and body-worn wireless medical technologies have increased the demand for spectrum (and for greater flexibility in how such devices operate and coexist). The FCC's Report and Order replaces the existing Medical Implant Communications Service ("MICS") with a new Medical Device Radiocommunication Service ("MedRadio"). The MedRadio service remains under Part 95 of the Commission's rules and maintains most of the technical rules of the MICS service in the spectrum previously allocated for MICS (402–405 MHz), but adds additional adjacent spectrum (401–402 MHz and 405–406 MHz). Altogether, the MedRadio Service will provide a total of 5 MHz of contiguous spectrum on a secondary basis for advanced wireless medical radio communication devices. The spectrum is generally harmonized with standards in Europe to take advantage of economies of scale, and to provide assurances that international travelers should not experience harmful interference when using the devices outside of the United States.

As a result, medical device manufacturers have more spectrum options, and, the additional 2 MHz spectrum may enable the certification of new medical devices by the FCC's Office of Engineering and Technology.

Implanted Neuromuscular Stimulator NPRM

The FCC proposes to allot spectrum and adopt service and technical rules for new implanted medical devices that would expand the use of functional electric stimulation to restore sensation, mobility and function to paralyzed limbs and organs. This additional allotment for electronic stimulation technologies could be used to develop devices for the medical treatment for millions of people living with brain and spinal cord injuries and neuromuscular disorders, such as multiple sclerosis, polio, cerebral palsy and Lou Gehrig's Disease. These implanted neuromuscular micro stimulators would function as wireless broadband medical micro-power networks ("MMNs") within a patient. By eliminating the wires now used to interconnect multiple implanted neuromuscular micro stimulators and the external power source for the implants, MMNs would greatly reduce the risk of infection and increase patient mobility and system reliability. The Notice seeks comment on the feasibility of allowing up to 20 MHz of spectrum in the 413–457 MHz band to be used under the Medical Device Radiocommunication Service ("MedRadio Service") in Part 95 of the Commission's rules, and seeks comment on the allocation of four specific segments for this purpose: 413–419 MHz, 426 432 MHz, 438–444 MHz, and 451–457 MHz. The Notice also seeks comment on the prospective service and technical rules that would govern MMN operations, such as transmitter power, emission bandwidth, duty cycle, contention protocols, and other operating specifications that generally comport with the framework of the existing MedRadio Service. The Notice proposes to limit MMN operations to use only by persons for diagnostic and therapeutic purposes, and only to the extent provided under the direction of authorized health care professionals.

This NPRM has not been published yet in the *Federal Register*, but comments are due 90 days after publication. Replies are due 120 days after publication in the *Federal Register*.

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If you are interested in registering new devices under the FCC's Order, or in commenting on the additional spectrum allotment for electronic stimulation technologies, please contact one the authors or the Reed Smith attorney with whom you normally work.

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