Federal Communications Commission
Washington, D.C. 20554

November 20, 2009

DA 09-2425

Mitchell Lazarus
Counsel for EnteroMedics Inc
Fletcher, Heald & Hildreth, P.L.C.
1300 North 17th Street, 11th Floor
Arlington, VA 22209

Dear Mr. Lazarus:

This is in response to your request of October 6, 2008, filed on behalf of EnteroMedics™ Inc. (EnteroMedics) for a waiver of Section 15.209 of the Commission's Rules, 47 C.F.R. § 15.209, to permit EnteroMedics to obtain FCC certification for and market its Maestro™ RC and RF models of implantable medical devices.[1] You state that these devices are surgically implanted in the body and are used for the treatment of gastro-intestinal disorders such as obesity, diabetes, pancreatitis, and inflammatory bowel disease by disrupting communications between the vagus nerve and the brain. The implanted Maestro device receives both power and communications signals – either separately or simultaneously, depending on the model – from an external Controller that operates at a frequency of 6.78 MHz and is connected by a short cable to an external antenna attached to the skin.[2] The 6.78-MHz signal is centered in the 6.765-6.795 MHz (6.78-MHz) industrial, scientific, and medical (ISM) band.[3]

You also state that the Controller transmits a power signal on this frequency via the external antenna to the implanted device in compliance with the Commission's Part 18 Rules for ISM equipment.[4] You further indicate that the Controller transmits a communications signal to the

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[1] *See* EnteroMedics Inc., Request for Waiver of Section 15.209 of the Commission's Rules to Permit the Marketing of Implantable Devices for the Treatment of Gastro-Intestinal Disorders (Request) dated October 6, 2008, from Mitchell Lazarus, Fletcher, Heald & Hildreth, P.L.C.

[2] *See* Request at 1-2, 4-6. The RC model Controller operates in either "charging mode" or "programming mode," but not at the same time. The RF model Controller simultaneously powers and programs the implanted device in real time but does not charge a battery. *See* Request at 6.

[3] The 6.78-MHz band – designated for ISM use – is part of the 6.765-7000 MHz band, which is allocated to fixed and mobile, except aeronautical mobile route, services on a primary basis for Federal and non-Federal users, and is authorized for Private Land Mobile radio services. In addition, under United States Footnote 340 (US340), the 2-30 MHz band is available on a non-interference basis to Federal and non-Federal maritime and aeronautical stations for the purpose of measuring the quality of reception on radio channels. *See* 47 C.F.R. § 2.106, International Footnote 5.138, US340, and § 18.301. Under Part 18 of the Commission's Rules, there is no power limit for in-band ISM operations in the 6.78-MHz ISM band. *See* 47 C.F.R. § 18.305. Under Part 15 of the Commission's Rules, unlicensed intentional radiators may also be operated in the 6.78-MHz band. *See* 47 C.F.R. § 15.209.

[4] When the RC Controller is charging the implanted device's battery, its operation complies with Part 18. When the RF Controller's signal is not modulated (*i.e.*, no communications are transmitted with the power), its operation also complies with Part 18. *See* Request at 6. *See also* EnteroMedics' October 28, 2008, *Ex Parte* presentation at 7.

implanted device via the external antenna on the same frequency as the power transmission (either separately or simultaneously, as noted *supra*) and that the level of the communications signal exceeds the limit for unlicensed intentional radiators contained in Section 15.209 of the Commission's Rules.[5] Specifically, Section 15.209 limits the emissions of unlicensed intentional radiators operating within the 1.705-30 MHz band to a field strength of 30 microvolts per meter (uV/m) at a measurement distance of 30 meters (-45.7 dBm).[6] The Maestro external RC model device operates with communications emissions of approximately 63.3 uV/m at 30 meters (-39.2 dBm) and the external RF model device operates with communications emissions of approximately 200.2 uV/m at 30 meters (-29.2 dBm).[7] You request that we waive Section 15.209 to permit EnteroMedics' Maestro RC and RF devices to operate with emissions at these levels, respectively.

In support of your request, you state EnteroMedics is limited in its choice of bands in which to operate because delivery of power to the implanted Maestro device requires use of an ISM band. You further state that the 6.78-MHz ISM band is particularly well suited to the spectrum and operation needs of the Maestro devices. You indicate that EnteroMedics could design a fully compliant device by using a different frequency where more power is permitted for the communication function so these transmissions comply with the Commission's Rules. Doing so, however, would require an additional antenna and more circuitry in the implanted device to accommodate the second frequency. The result would be a larger, heavier, and more costly device. In addition, you state that the Section 15.209 power levels at 6.78 MHz are too low for reliable communications between the external controller and the implanted device.[8]

In further support of your request, you state that EnteroMedics' devices will not affect users in other bands because the sidebands that are produced by modulating their 6.78-MHz carrier frequency lie entirely within the 6.78-MHz ISM band and comply with the Section 15.209 limits. Moreover, you submit that all the external devices' out-of-band and spurious emissions comply with the Section 15.209 limits as well. In addition, you argue that EnteroMedics' devices are unlikely to interfere with licensed Private Land Mobile services in the 6.78-MHz band because most of that band's licensees are using transmitters that operate at, or well above, 100 Watts.[9] You contend that interference to any licensed communications would hardly be possible because EntroMedics' devices' very low-powered transmissions have a maximum operating range of approximately seven centimeters and the signals are directed into a user's body instead of being intentionally radiated into space.[10] You also point out that, hypothetically, if an EnteroMedics device used different circuitry to produce separate compliant power and communications signals and these signals were simultaneously transmitted on the 6.78-MHz center frequency, then the

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[5] *See* Request at 2, 6-7.

[6] *See* 47 C.F.R. § 15.209.

[7] *See* Request at 6-7. The RF model's communications emissions are higher than the RC model's because it provides power during the communications. *See* EnteroMedics' October 28, 2008, *Ex Parte* presentation at 6.

[8] *See* Request at 7.

[9] *See* Request at 8-9.

[10] *See* EnteroMedics' March 10, 2009, *Ex Parte* presentation at 10.

resultant combined signals would be indistinguishable from the operations for which EnteroMedics is seeking a waiver.[11]

In your request, you also contend that granting a waiver to EnteroMedics would be in the public interest because it would offer physicians and their patients an additional option for promoting weight loss that appears to be not only both safer and more effective than several methods presently in use, such as drug therapy, gastric bypass surgery, and laparoscopic banding, but would likely be preferred by many patients over more invasive surgical approaches. Moreover, you state that a grant of EnteroMedics' waiver could increase the number of patients who can manage their obesity and its co-morbid consequences, thereby saving lives, reducing health-care spending, and enhancing the quality of life for many people.[12] Finally, you argue that because EnteroMedics' waiver request is consistent with the purpose of Section 15.209 in controlling interference from unlicensed radio communications to other users and would further the public interest by providing a badly needed life-saving therapy, it would fit easily within the boundaries established by *WAIT Radio*.[13]

We are authorized to grant a waiver under Section 1.3 of the Commission's Rules if the petitioner demonstrates good cause for such action.[14] Good cause, in turn, may be found and a waiver granted "where particular facts would make strict compliance inconsistent with the public interest."[15] To make this public interest determination, the waiver cannot undermine the purposes of the rule, and there must be a stronger public interest benefit in granting the waiver than in applying the rule.[16]

Based on the submissions presented in this request, we find that a waiver permitting the RC and RF models of EnteroMedics' unlicensed external power/communications devices to operate in the 6.78-MHz band with emissions higher than those permitted by Section 15.209 of the Commission's Rules up to the levels indicated above is warranted. We believe that the purpose underlying the emission limit in the Rules would not be served by applying it to EnteroMedics' devices since it is unlikely that either Federal or non-Federal licensees in the 6.78-MHz band will experience interference from operation of these devices at the power levels and operating conditions indicated. We also note that the power transfer function of EnteroMedics' devices is compliant with the requirements for medical implant devices contained in Part 18 of the

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[11] *See* Request at 8.

[12] *See* Request at 10-11.

[13] *See* Request at 12, citing *WAIT Radio v. FCC*, 418 F.2d 1153 (D.C. Cir. 1969).

[14] *See* 47 C.F.R. § 1.3. *See also ICO Global Communications (Holdings) Limited v. FCC*, 428 F.3d 264 (D.C. Cir. 2005); *Northeast Cellular Telephone Co. v. FCC*, 897 F.2d 1164 (D.C. Cir. 1990); *WAIT Radio v. FCC*, 418 F.2d 1153 (D.C. Cir. 1969).

[15] *Northeast Cellular*, 897 F.2d at 1166; *see also ICO Global Communications*, 428 F.3d at 269 (quoting *Northeast Cellular*); *WAIT Radio*, 418 F.2d at 1157-59.

[16] *See, e.g.*, *WAIT Radio*, 418 F.2d at 1157 (stating that even though the overall objectives of a general rule have been adjudged to be in the public interest, it is possible that application of the rule to a specific case may not serve the public interest if an applicant's proposal does not undermine the public interest policy served by the rule); *Northeast Cellular*, 897 F.2d at 1166 (stating that in granting a waiver, an agency must explain why deviation from the general rule better serves the public interest than would strict adherence to the rule).

Commission's Rules. Furthermore, the intended use and the short distance between the implanted device and the external Controller's antenna will keep the power requirements necessary for successful communications low which, in turn, will minimize the potential for interference.

Moreover, we recognize that the medical implant components of these devices are designed to operate optimally and less intrusively by performing the communication and power transfer functions at a single frequency, and we conclude that no useful purpose would be served by requiring that these functions be performed on separate frequencies for this type of device. In addition, we note that there is no more interference potential from allowing the EnteroMedics devices' communication signal emissions to exceed the limit specified in Section 15.209 than if the devices used different circuitry to generate separate compliant power and communication signals that were simultaneously transmitted at 6.78 MHz. Thus, given the devices' intended use and the limited interference potential, we conclude that a waiver of the emission limits of Section 15.209 is warranted. This waiver applies only to these specific medical implant devices, however, and is not to be considered to apply generally to other devices.

We also conclude that grant of a waiver to EnteroMedics will serve the public interest by providing physicians and their patients an additional option for safely and effectively promoting weight loss. In turn, this could help increase the number of patients who can manage their obesity and its co-morbid consequences, could save lives and reduce health-care spending, and could enhance the quality of life for many people.

Accordingly, pursuant to the delegated authority in Sections 0.31, 0.241, and 1.3 of the Commission's Rules, 47 C.F.R. §§ 0.31, 0.241, 1.3, we waive the requirements of Section 15.209 of our Rules to allow EnteroMedics to obtain FCC certification for and market its Maestro RC and RF models of implantable medical devices that operate in the 6.78-MHz band with external emissions not to exceed 63.3 uV/m at 30 meters and not to exceed 200.2 uV/m at 30 meters, respectively.

Sincerely,

Julius P. Knapp
Chief
Office of Engineering and Technology