



Via Electronic Filing

August 21, 2008

Marlene H. Dortch, Secretary
Federal Communications Commission
445 12th Street SW
Washington, DC 20554

Re: *Written Ex Parte: Investigation of the Spectrum Requirements for Advanced Medical Technologies – ET Docket No. 06-135; Amendment of Parts 2 and 95 of the Commission’s Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz – RM-11271*

Dear Ms. Dortch:

In recent filings in the above-referenced dockets, St. Jude Medical and its wholly-owned subsidiary, Advanced Neuromodulation Systems, Inc. (collectively, “St. Jude Medical”), urged the Commission to adopt MedRadio rules that permit body-worn transmitters connected percutaneously to a surgically implanted medical device to operate on a temporary basis at 402-405 MHz if certain conditions are met.¹ St. Jude Medical explained that its proposal would serve the public interest by enhancing the therapeutic and diagnostic options available to patients and doctors and minimizing health care costs, while posing little if any risk of harmful interference to fully implanted devices operating at 402-405 MHz.

In a letter dated August 6, 2008, Medtronic indicated that it would be amenable to St. Jude Medical’s proposal, provided that three clarifications are included in any revised FCC rules.² St. Jude Medical appreciates the constructive input of Medtronic and finds Medtronic’s proposed clarifications to be acceptable.

¹ Letter from Kathleen M. Chester, St. Jude Medical, to Marlene H. Dortch, FCC, ET Docket No. 06-135, RM-11271 (July 17, 2008) (“St. Jude Letter”); Letter from Richard D. Mallen, counsel for Advanced Neuromodulation Systems, Inc., to Marlene H. Dortch, FCC, ET Docket No. 06-135, RM-11271 (July 17, 2008) (“ANS Letter”) (attaching presentation used during meeting with the FCC’s Office of Engineering and Technology on July 16, 2008).

² Letter from David E. Hilliard, counsel for Medtronic, to Julius Knapp, Chief of the FCC’s Office of Engineering and Technology, ET Docket No. 06-135, RM-11271, at 2-3 (August 6, 2008) (“Medtronic Letter”).

In fact, two of the clarifications suggested by Medtronic are virtually identical to conditions that St. Jude Medical already proposed.³ In particular, St. Jude Medical already made clear – and thus fully agrees with Medtronic – that any temporary body-worn device operating at 402-405 MHz (i) must comply fully with any MedRadio requirements governing implanted medical transmitters operating at 402-405 MHz,⁴ including all listen-before-talk and adaptive-frequency-agility requirements; and (ii) must cease all transmissions following a brief evaluation period, which may not exceed 30 days,⁵ and be intended to be replaced by a fully implanted permanent transmitter after the evaluation period.

In its August 6 letter, Medtronic also agreed with St. Jude Medical that any temporary body-worn transmitter should operate at an appropriate measured field strength limit to account for the lack of body absorption of radiated power that occurs with implanted transmitters.⁶ Here, however, Medtronic went further by proposing a specific power limit – 200 nW EIRP – that the temporary body-worn transmitter should not exceed.⁷ St. Jude Medical finds this power limit to be reasonable. Thus, if the Commission so desires, it should adopt MedRadio rules that specify a 200 nW EIRP power limit for body-worn transmitters operating during the evaluation period within the 402-405 MHz band.

As the foregoing makes clear, Medtronic and St. Jude Medical are in agreement on the rule changes needed to accommodate temporary body-worn transmitters operating at 402-405 MHz. On one key point, however, Medtronic's August 6 letter must be corrected. Specifically, Medtronic claimed that "St. Jude Medical's temporary external application is better suited for the proposed 401-402 and 405-406 MHz wing bands."⁸ In fact, the wing bands would not be suitable for at least two reasons.⁹ First, relegating the temporary body-worn transmitters to the wing bands would undermine the very purpose of the body-worn evaluation period, which is to permit doctors and patients to assess the clinical benefit of medical devices prior to full implantation. If the temporary body-worn transmitters were required to operate at 401-402 and 405-406 MHz, their performance on

³ See St. Jude Letter at 2; ANS Letter, Att. at 10.

⁴ Although Medtronic stated that "the external device must comply fully with the *existing MICS rules*," Medtronic Letter at 3 (emphasis added), St. Jude Medical assumes that what Medtronic meant to say was that the external device must comply fully with *all MedRadio rules* in effect after the conclusion of this rulemaking proceeding. Of course, prior to the conclusion of this proceeding, all devices must comply with the MICS rules currently in effect.

⁵ St. Jude Medical suggested 30 days as a reasonable time period for this condition, and thus agrees with Medtronic that it would be appropriate for the FCC to adopt a rule that limits the evaluation period to no more than 30 days.

⁶ See Medtronic Letter at 3.

⁷ *Id.*

⁸ *Id.* at 2.

⁹ See St. Jude Letter at 2; ANS Letter, Att. at 12.

that spectrum might not accurately predict their performance on the different frequencies (402-405 MHz) that they would occupy after full implantation. As a result, the evaluation period would no longer give doctors and patients confidence that they could identify those patients for whom full implantation is appropriate.

Second, relegating the temporary body-worn devices to the wing bands could significantly impair the performance of these devices. Many of the radios permanently operating in the wing bands will have much higher power emissions than the temporary body-worn transmitters proposed by St. Jude Medical, which will be designed to be implanted and be subject to constraints in size and battery power. These higher emission levels could cause unacceptable interference to temporary body-worn devices, and could force temporary transmitters to expend energy looking for an available channel or prevent them from finding one altogether. In addition, the channels in the proposed wing bands likely will be too narrow to accommodate many temporary body-worn devices, which will be designed to operate post-implantation on the wider channels in the core spectrum at 402-405 MHz.

Given the unsuitability of the wing bands for the temporary body-worn application proposed by St. Jude Medical, the Commission should modify its existing rules to permit that application to operate in the core spectrum at 402-405 MHz, as proposed herein and in St. Jude Medical's prior filings. Medtronic and St. Jude Medical agree on the rule modifications needed to achieve that goal, and no party has voiced opposition.

Pursuant to the Commission's rules, this letter is being submitted for inclusion in the public record of the above-referenced proceedings.

Sincerely,



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Kimberley Elting
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