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**VIA ELECTRONIC FILING**

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

**Re: ET Docket Nos. 06-135, 05-213, 03-92 and RM-11271  
*Ex Parte* Presentation**

Dear Secretary Dortch:

Medtronic, Inc., comments on ON Semiconductor Corporation's ("ON Semi's") December 19, 2008, filing relating to its newly revised request that the FCC permit wireless hearing aids and streaming audio applications in 300 kHz of the upper MEDS wing band at 405-406 MHz.

The medical device industry and an RF transceiver chipmaker strongly oppose allowing audio applications in this spectrum because it would impair the usefulness of the band for wireless medical body area systems comprised of body-worn and implantable devices.<sup>1</sup> Should the FCC nonetheless decide to consider ON Semi's request to allow wireless audio applications in the band, it should do so only after it develops a full record via a notice of proposed rulemaking. This is the path that the Commission appropriately followed for the well established Medical Implant Communications Service ("MICS")<sup>2</sup> and for the proposed MEDS service, which is now ripe for FCC approval.

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<sup>1</sup> See Medtronic *Ex Parte* Filings (Sept. 25, 2008; Oct. 21, 2008; Nov. 20, 2008, Dec. 2, 2008); Zarlink *Ex Parte* Filing (Oct. 27, 2008); see also AdvaMed Comments (Dec. 6, 2006) ("The existing MICS band rules prohibiting the transmission of voice (i.e., 95.631(h)) should be maintained for the core and wing bands."). AdvaMed is a medical device industry trade association whose members include Biotronik, Boston Scientific/Guidant, Medtronic, and St. Jude Medical.

<sup>2</sup> MICS supports wireless communications from implantable medical devices in the "core" 402-405 MHz band. See Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band, *Report and Order*, 14 FCC Rcd 21040 (1999).

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Medtronic petitioned the FCC to establish the Medical Data Service (“MEDS”) three and a half years ago.<sup>3</sup> The MEDS Rulemaking Petition, which contained detailed regulations for the new service, received wide support from medical professionals, medical device manufacturers, and an RF transceiver manufacturer.<sup>4</sup> As is the case with the established MICS rules as well as the Wireless Medical Telemetry Service and the proposed Medical Body Area Network Service at 2360-2400 MHz,<sup>5</sup> the proposed MEDS rules are limited to non-voice applications because audio is a high-duty-cycle application which, if permitted, would prevent spectrum access or interfere with countless MEDS users in the band.

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<sup>3</sup> See Medtronic Petition for Rulemaking to Amend Parts 2 and 95 of the Commission’s Rules to Establish The Medical Data Service at 401-402 and 405-406 MHz, RM-11271 (July 15, 2005) (“MEDS Rulemaking Petition”). The Petition was filed after the European process was well underway. In March 2004, ETSI ERM\_TG30 “Wireless Medical Devices” initiated a New Work Item (“NWI”) to develop a Technical Report for the MEDS allocation, which was followed up by publication of ETSI Technical Report TR 102 343 V1.1.1 in July 2004. CEPT published the MEDS spectrum allocation in ERC/REC 70-03 Annex 12 Subbands a1 and a2 in February 2007. ETSI then published the MEDS Standard specifying requirements for use of the bands in December 2007. In November 2008, the product specific Harmonized Standard EN 302 537-2 was published in the Official Journal of the EU. Thus, the MEDS item, which received unanimous support, progressed from NWI to Harmonized Standard in about 4.5 years. In contrast, the wireless hearing aid proposal for a Technical Report to be developed in ETSI, *see* [http://webapp.etsi.org/WorkProgram/Report\\_WorkItem.asp?WKI\\_ID=28847](http://webapp.etsi.org/WorkProgram/Report_WorkItem.asp?WKI_ID=28847), does not reference use of the 401-406 MHz band because a formal objection was lodged by ETSI ERM\_TG30 and sustained. Given the opposition to ON Semi’s proposal in Europe due to its interference potential and aggressive spectrum occupancy requirement, it is highly unlikely that the proposal will be formally approved within similar time frame as MEDS – if at all. Before ETSI can evaluate permitting wireless hearing aids at 405-406 MHz, CEPT must approve and carry out a compatibility study based on an ETSI Technical Report to demonstrate coexistence between audio devices and MEDS and MICS devices.

<sup>4</sup> See Sept. 23, 2005 Comments and Oct. 11, 2005 Reply Comments in RM-11271.

<sup>5</sup> See 47 C.F.R. §§ 95.410(d) & (e); 95.631(h) & (i), 95.1115(c), 95.1117(a); GE Healthcare Comments at 18-23 (Dec. 27, 2007).

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The FCC released the *MedRadio NPRM* in July 2006 proposing to allocate the 401-402 and 405-406 MHz wing bands for wireless body-worn and implantable medical devices and associated external equipment, consistent with the MEDS Rulemaking Petition.<sup>6</sup> Use of the wing bands for audio carriage was not raised in the *NPRM*.<sup>7</sup>

In October 2007, ON Semi proposed using the upper wing band for “ear to ear” hearing aid communications and “peripheral device to hearing aid(s)” communication.<sup>8</sup> ON Semi expressly recognized that audio applications would have “a duty cycle of up to 100%”<sup>9</sup> and requested that the upper wing band be partitioned into three 300 kHz spectrum blocks for audio devices that could operate at the maximum allowable power level of 25  $\mu$ W (-16 dBm) EIRP.

Since that time, the limited details that ON Semi has disclosed regarding its proposed audio applications have been modified repeatedly. Thus, its plans remain a work in progress. Recently, ON Semi changed its request for three 300 kHz blocks (at -16 dBm EIRP) to one 300 kHz block in the upper wing band (at -36 dBm EIRP).<sup>10</sup> In its most recent filing, ON Semi proposes a lower transmit power level of -41 dBm EIRP while acknowledging that certain audio applications would still operate at the maximum -16 dBm EIRP power level.<sup>11</sup>

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<sup>6</sup> See *Investigation of the Spectrum Requirements for Advanced Medical Technologies; 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*, ET Docket No. 06-135, NPRM, NOI, & Order, FCC 06-103 (July 18, 2006) (“*MedRadio NPRM*”).

<sup>7</sup> The issue of allowing emissions in the MedRadio band from other than non-voice communications was raised only in the *Notice of Inquiry* portion of the *NPRM*. See ¶ 39. Thus, if the issue of whether to allow voice communications, currently prohibited in the FCC’s MICS rules and ETSI rules governing 401-406 MHz operations, is to be considered further, additional study must be undertaken.

<sup>8</sup> See AMI Semi Comments (Oct. 20, 2007) at 2.

<sup>9</sup> See *id* at 2.

<sup>10</sup> See ON Semi Ex Parte Presentation (Sept. 18, 2008).

<sup>11</sup> See ON Semi Ex Parte Presentation (Dec. 19, 2008). ON Semi describes an authorization in Germany to permit wireless hearing aids in the core band at





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