



1776 K STREET NW
WASHINGTON, DC 20006
PHONE 202.719.7000
FAX 202.719.7049

7925 JONES BRANCH DRIVE
McLEAN, VA 22102
PHONE 703.905.2800
FAX 703.905.2820

www.wileyrein.com

David E. Hilliard
202.719.7058
dhilliard@wileyrein.com

John W. Kuzin
202.719.3506
jkuzin@wileyrein.com

April 28, 2008

VIA ECFS AND E-MAIL

Julius Knapp
Chief of the Office of Engineering and Technology
Federal Communications Commission
445 12th Street, SW
Washington, DC 20554

**Re: *Ex Parte* Filing - 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 Data Service at 401-402 and 405-406 MHz – RM-11271**

Dear Mr. Knapp:

Medtronic hereby responds to the recent *ex parte* submissions from Transoma Medical in the above-referenced dockets seeking to expand the allowable uses for the core MICS 402-405 MHz band and proposed MEDS 401-402 and 405-406 MHz wing bands to include animal testing in “laboratory environment[s] for the purpose of discovery, development, and testing of pharmaceuticals, medical devices and surgical techniques.”¹

As explained herein, the Commission should reject Transoma’s request because: (1) the 401-406 MHz band is in its nascent stages, as the FCC has stated, and allowing animal testing for “the purpose of discovery” could have grave consequences on the successful growth of the band for its intended purposes, namely, the medical treatment of human patients; (2) it would create an exception that could swallow the current circumscribed applications that require a duly authorized healthcare professional and human patient; (3) the device testing that Transoma wants to conduct can be supported in other spectrum, and to the extent animal testing needs to be at 401-406 MHz, Transoma and those who would use its equipment should seek experimental authority; and (4) the issue was not raised in the MedRadio NPRM and promulgating rules that permit use of the band for animal testing would violate Administrative Procedure Act (“APA”) notice and comment requirements.

¹ Transoma *Ex Parte* Letter (Aug. 23, 2007) at 3. See Transoma *Ex Parte* Communications, Apr. 10, 2008 and Apr. 22, 2008.

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1. The MedRadio band should be used in the direct treatment of human patients.

Given the nascent stage of low-power medical device deployment in these bands, now is not the time to expand the allowable types of uses beyond what is currently permitted (and what has been proposed), namely RF medical devices that licensed health care providers use in the care and treatment of patients.²

In promulgating the MICS rules and in proposing the MEDS rules, the FCC set aside a limited amount of spectrum for use by RF medical devices implanted in and worn by patients, and rejected calls to open the band to any and all types of communications that may have a remote connection to healthcare.³ Transoma itself has recognized the importance of wireless medical devices in the band for it “will allow physicians to determine [human patient] status ... in real time – providing for early detection of events that may threaten the patient’s life or lead to hospitalization.”⁴

Transoma’s request to allow the MedRadio band to be used “to monitor a research subject [such as an animal] for the purpose of improving human health”⁵ is unlimited in scope and would permit a broad spectrum of applications well beyond the Commission’s intention in establishing the MICS and proposed MedRadio rules.

2. Transoma’s proposed rule expansion is overbroad and unworkable, and thus raises serious concerns regarding the impact on human patients. There are two main reasons why it will be difficult (if not impossible) for the FCC to restrict the use of MedRadio devices to genuine medical testing in animals as a practical matter.

² See Appendix 1 to Subpart E to Part 95, Glossary of Terms (MICS regulations carefully drawn to provide for the transmission of data to “protect the safety and well-being of the person” in whom medical devices have been implanted); see also MEDS Petition for Rulemaking, RM-11271 (July 15, 2005).

³ See Investigation of the Spectrum Requirements for Advanced Medical Technologies, *Notice of Proposed Rulemaking, Notice of Inquiry, and Order*, ET Docket No. 06-135, 21 FCC Rcd 8164, 8167 ¶ 7 (2006) (“The MICS service was anticipated to transmit data in support of the diagnostic and/or therapeutic functions associated with implanted medical devices to enable individuals and medical practitioners to utilize potential life-saving medical technology without causing interference to other users of the spectrum.”).

⁴ See Comments of Transoma Medical on Petition for Rulemaking, RM-11271 (Sept. 27, 2005).

⁵ Transoma *Ex Parte* Presentation (Sept. 28, 2007) at 3. See also Transoma *Ex Parte* Communication (Apr. 22, 2008) at 1 (requesting allowance for “research specifically directed to the betterment of human health”).

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First, Transoma’s proposal to limit animal use of RF medical devices to “laboratory environments” for purposes of “discovery,” “development,” and “testing” is extremely broad. It fails to account for the humans equipped with MedRadio devices that work at, live near, or pass by animal laboratories. In addition, “laboratory environments” can exist in residential settings, office buildings, and healthcare facilities – all places where human patients will be. Indeed, Transoma’s latest proposal to permit operation at *any* location that is 20 meters away from a “hospital, clinic, or other health care facility” is even broader and therefore even more troubling.⁶

Second, Transoma’s proposal to allow RF communications that relate in any way to discovery and testing of pharmaceuticals, medical devices and surgical techniques is impermissibly vague and would increase exponentially the use of the band. When RF devices are used for purposes of discovery and testing, they tend to be configured to use spectrum much more intensively and transmit at the maximum allowable power (for test units are not constrained in the same way as devices implanted in humans, which need to conserve battery power for therapy and thus transmit using the least amount of power to ensure reliable communications).

Transoma’s stated need for “[g]reater telemetry range” and “simultaneous multiple channels with duplex operation” and “greater spectrum bandwidth” to support its testing raise serious concerns regarding its ultimate plans for the MedRadio band, and introduces the prospect of use by other inventors who would broadly interpret a regulation permitting communications for RF tests and discoveries that “improv[e] human health.”⁷

3. The Transoma devices should operate in other spectrum or pursuant to experimental authority at 401-406 MHz. Transoma can operate its devices pursuant to Part 15. Operations under Section 15.231, for example, can be conducted very close to the MedRadio band at 418 MHz.⁸ Moreover, the isolated

⁶ See Transoma *Ex Parte* Communication (Apr. 22, 2008) at 1.

⁷ See Transoma *Ex Parte* Communication (Sept. 28, 2007) at 12.

⁸ See 47 C.F.R. § 15.231. Transoma’s “[e]xternal-to-implant link ... used for low-duty-cycle communication involving configuration, control, and data acknowledgment” can be supported under Section 15.231(a). Transoma Sept. 28, 2007, *Ex Parte* Presentation at 17; see also 47 C.F.R. § 15.231(a) (“Data is permitted to be sent with a control signal.”). Section 15.231(e) could support the implant to external unit data link. A great deal of latitude exists for formulating a transmission protocol to address Transoma’s requirements within the Section 15.231(e) framework of a minimum
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lab facilities where (according to Transoma) animal testing would occur provide an environment where 418 MHz communications may work quite well.⁹

To the extent Transoma and those who would use its devices need to conduct experiments with devices implanted in (or placed on or near) animals in the 401-406 MHz MedRadio band, the experimental rules provide a ready solution. The FCC should allow operation of compliant devices pursuant to experimental authorization with specific authority to permit marketing. This is a workable approach given the usage model and number of transceivers that Transoma has proposed for animal testing. *See* Transoma August 23, 2007 *Ex Parte* Letter (testing in roughly 300 university, medical, and pharmaceutical laboratories).¹⁰ In this way, the FCC can better monitor the areas in which RF animal testing will be conducted while MedRadio devices are deployed more widely. The experimental licensing process also would serve to remind those responsible for supervising such use that MedRadio device operation inside, on, and near humans takes precedence over animal usage.

Medtronic recognizes that the carefully controlled testing of medical devices and pharmaceuticals in animal subjects is useful to the overall development of medical devices, but expanding the allowable uses for MedRadio devices in the manner suggested by Transoma is unnecessary and would create an exception that could swallow the rule.

4. Any rule permitting animal testing in the MedRadio band at this time would violate APA notice and comment requirements. Before the Commission may adopt rules permitting animal testing in the MedRadio band, it must first provide notice and seek comment on the impact of such an expansion via a notice of proposed rule making (“NPRM”), which has not been done. *See* 5 U.S.C. § 553(b). Transoma concedes that the issue was not raised in the MedRadio NPRM. Its bald

10 second off period with a silent period of 30 times the on time. Further, with a field strength limit of 4.1 mV/m at 3 meters as measured with a device employing an average detector function coupled with a 20 dB duty cycle factor permitted for Section 15.231(e) equipment, the peak pulse power permitted is higher than that now permitted in the MICS band or proposed for the MEDS bands.

⁹ *See, e.g.*, Transoma *Ex Parte* Presentation (Nov. 30, 2007) at 2.

¹⁰ Indeed, Section 5.3(c) expressly provides for the issuance of experimental authorizations in order to provide “communications essential to a research project.” 47 C.F.R. § 5.3(c) (2007).

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assertion that animal testing is nonetheless a “logical outgrowth” of the MedRadio NPRM and satisfies APA notice requirements is incorrect.¹¹ The “logical outgrowth” doctrine does not extend to a final rule that finds no roots in the agency’s proposal because “*something is not a logical outgrowth of nothing.*” *Kooritzky v. Reich, Secretary of Labor*, 17 F.3d 1509, 1513 (D.C. Cir. 1994) (emphasis supplied). Moreover, the APA’s notice requirements are not satisfied when a party proposes entirely new concepts well after the conclusion of the NPRM’s notice and comment period, as Transoma is doing here.¹²

Using the band to support the “discovery, development, and testing of pharmaceuticals, medical devices and surgical techniques” in animals opens up a whole host of questions and issues that were not dealt with pursuant to the requirements of the APA. Transoma did not even raise the issue of animal testing in comments that it filed on the MEDS Petition for Rulemaking in the Fall of 2005.¹³ Transoma brought the issue to the Commission’s and the public’s attention in an August 2007 *ex parte* letter – more than eight months after the MedRadio NPRM comment cycle ended.¹⁴ Accordingly, Transoma’s proposed expansion of the

¹¹ See *Environmental Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (quoting *Ne. Maryland Waste Disposal Auth. v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004) (final rule is a “‘logical outgrowth’ of a proposed rule only if interested parties ‘should have anticipated that the change was possible, and thus *reasonably should have filed their comments on the subject* during the notice-and-comment period’”) (emphasis supplied) (internal quotations and citations omitted).

Transoma’s further assertion that the NPRM did not include proposed rule language specifying human implants does not cure Transoma’s more basic problem that the NPRM did not raise animal testing. See Transoma Ex Parte Presentation (Apr. 22, 2008) at 2. Transoma’s attempt to rest its case on general statements in the NPRM that the band will accommodate a “variety of new medical devices” and the “development of newer, more capable, and more sophisticated devices,” *id.* at 3 citing NPRM ¶¶ 1-2, serves to underscore Medtronic’s point that the current requirements must be maintained to successfully support this expected growth in low-power RF medical devices operating in, on and near human patients.

¹² See Revision of Part 15 of the Commission’s Rules Regarding Ultra-Wideband Transmission Systems, *Memorandum Opinion and Order*, ET Docket No. 98-153, 18 FCC Rcd 3857, ¶ 48 (2003) (rejecting new rule filed well after the comment cycle ended that was “beyond the scope of the issues addressed thus far in th[e] proceeding”).

¹³ See Comments of Transoma Medical on Petition for Rulemaking, RM-11271 (Sept. 27, 2005) (“[W]e urge the FCC to go forward with developing regulations to permit the MEDS services in Part 95 as rapidly as possible.”).

¹⁴ See Transoma Ex Parte Presentation (Aug. 23, 2007) at 3.

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MedRadio rules to permit animal testing should be rejected in accordance with firmly established federal court and FCC APA precedent.¹⁵

In conclusion, the Commission should reject Transoma Medical's request to allow animal testing in the 401-406 MHz MedRadio band based upon any (or all) of the foregoing reasons.

Sincerely,

David E. Hilliard

David E. Hilliard
John W. Kuzin

cc: Ira Keltz
Geraldine Matisse
Ron Repasi
Bruce Romano
Mark Settle
Alan Stillwell
Gary Thayer

¹⁵ See *Amendment of Part 101 of the Commission's Rules to Modify Antenna Requirements for the 10.7 - 11.7 GHz Band*, Report and Order, 22 FCC Rcd 17153, ¶ 24 (2007) (rejecting band segmentation proposal because affected parties were not given "an opportunity for meaningful and informed comment"); *Promoting Efficient Use of Spectrum Through Elimination of Barriers to the Development of Secondary Markets*, Third Report and Order, 22 FCC Rcd 7209, ¶¶ 10-12 (2007).