Federal Communications Commission 445 12th St., S.W. Washington, D.C. 20554

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DA 08-953 April 24, 2008

OFFICE OF ENGINEERING AND TECHNOLOGY TO TREAT EX PARTE COMMENTS OF GE HEALTHCARE AS PETITION FOR RULE MAKING AND SEEKS COMMENT

ET Docket No. 08-59

Comment Date: May 27, 2008

Reply Comment Date: June 11, 2008

On December 27, 2007, GE Healthcare (GEHC) filed *ex parte* comments in ET Docket No. 06-135 in response to a *Notice of Inquiry (NOI)* in the pending *MedRadio Proceeding*. ¹

In the *MedRadio Proceeding*, the Commission adopted a combined *Notice of Proposed Rulemaking (NPRM)* and *NOI*. In the *NPRM*, the Commission proposed to allocate additional spectrum in the 400 MHz band for implanted and body-worn medical devices using wireless radiofrequency (RF) technologies that are used for diagnostic and therapeutic purposes in human patients.² More specifically, the *NPRM* explored expanded use of such devices in the existing Medical Implant Communications Service (MICS) 'core' band at 402-405 MHz, as well as in the proposed new MedRadio 'wing' bands at 401-402 MHz and 405-406 MHz.

In the NOI, the Commission sought comment on the anticipated developments in the medical devices field and the resulting spectrum requirements of such devices that might use radio frequency (RF) transmitters. More particularly, the Commission asked for detailed

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¹ 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, DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules," ET Docket No. 06-135, RM-11271, Notice of Proposed Rulemaking and Notice of Inquiry and Order, (MedRadio Proceeding) 21 FCC Rcd 8164 (2006).

² The most common examples in present day use include cardiac pacemakers and blood glucose monitors. Commenters envision the use of such wireless devices in the treatment of many other medical conditions.

comment on new implant and body-worn medical radiocommunication technologies and how their operation could be accommodated.

Responding to the call for comments in the *NOI*, GEHC proposes the allocation of spectrum on a secondary basis in the 2360-2400 MHz band and for the adoption of service rules under Part 95 for the operation of wireless medical 'body sensor networks' - or BSNs. As described by GEHC, Wireless BSN sensors would be used to replace the present generation of physiological body sensors (often used with patients in hospitals, for example) that rely upon wired cables connected to bedside monitoring equipment. GEHC states that a key benefit of eliminating the wired link with wireless BSN technology would be to reduce the chances of body sensors becoming unintentionally disconnected, thereby enhancing the safety, quality and mobility of patient care. GEHC thus requests that the Commission issue a further rule making notice in order to consider its proposal.

Although the GEHC submission is styled as an *ex parte* comment, we conclude that it provides sufficient basis to be treated as a petition for rulemaking under Section 1.401 of the Commission's rules. Among other factors, it sets forth a comprehensive proposal for a new allocation in a specific frequency band and for service rules for a new Medical Body Area Network Service under Part 95, issues that are not presently under consideration in the *MedRadio Proceeding*. Thus, in order for the Commission to determine if there are sufficient reasons for instituting a rulemaking proceeding, we are treating the GEHC *ex parte* filing as a petition for rulemaking and seek comment on GEHC's request. To the extent the *ex parte* comment also discusses issues in the pending rulemaking, this public notice is issued without prejudice to the Commission's ability to address issues pending from the *NPRM* in the existing rulemaking. We deem the proceeding, for *ex parte* purposes, as "permit-but-disclose" in accordance with Section 1.1200(a) of the Commission's rules, subject to the requirements under Section 1.1206(b).

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR §§ 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) the Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998).

- Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: http://www.fcc.gov/cgb/ecfs/ or the Federal eRulemaking Portal: http://www.regulations.gov. Filers should follow the instructions provided on the website for submitting comments.
 - For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to ecfs@fcc.gov, and include the following words in

the body of the message, "get form." A sample form and directions will be sent in response.

Paper Filers: Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- The Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE, Suite 110, Washington, DC 20002. The filing hours at this location are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of <u>before</u> entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street, SW, Washington DC 20554.

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The full text of the GE Healthcare submission is available for inspection and copying during normal business hours in Room CY-A257, 445 12th Street, SW, Washington, D.C., and may also be purchased from the Commission's duplication contractor, Best Copy and Printing, Inc., (800) 378-3160.

Office of Engineering and Technology contact: Gary Thayer at (202) 418-2290.

By the Chief, Office of Engineering and Technology