



PUBLIC NOTICE

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

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DA 05-1670
June 15, 2005

OFFICE OF ENGINEERING AND TECHNOLOGY SEEKS COMMENT ON DEXCOM, INC. PETITION FOR A WAIVER OF PART 95 OF THE COMMISSION'S RULES FOR MEDICAL DEVICE

ET Docket No. 05-213

Comment Date: July 15, 2005
Reply Comment Date: August 1, 2005

On May 23, 2005, DexCom, Inc. (DexCom) filed a request for waiver of the frequency monitoring requirements of the FCC's Medical Implant Communications Service (MICS) rules (Part 95) for its blood glucose monitoring system.

DexCom states that its system is comprised of two devices: a short-term blood glucose monitoring sensor (STS) device and a long-term blood glucose monitoring sensor (LTS) device. DexCom indicates that it has requested Food and Drug Administration (FDA) pre-market approval for its STS device and that it plans by early next year to request similar approval for its LTS device. DexCom contends that, given the serious health and financial consequences of diabetics failing to manage their glucose levels adequately, the medical community and diabetics are anxious to have access to its system as soon as possible. However, DexCom states, its STS and LTS devices are incapable of satisfying the listen before transmit requirement that the MICS rules impose on all transmissions that do not constitute a medical implant event. DexCom therefore requests a waiver to permit its system to transmit periodically. DexCom further requests that the Commission act expeditiously on its waiver request so that it can move its system to market immediately upon FDA approval.

The FCC's Office of Engineering and Technology (OET) is seeking comment on this waiver request in order to develop a complete record on the issues presented by the request. For *ex parte* purposes, this proceeding will be treated as a "permit-but-disclose" proceeding, in accordance with Section 1.1200(a) of the Commission's rules, and is subject to the requirements under Section 1.1206(b) of the rules.

Pursuant to Sections 1.415 and 1.419 of the Commission's rules, 47 C.F.R. §§ 1.415, 1.419, interested parties may file comments on or before **July 15, 2005** and reply comments on or before **August 1, 2005**. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS) or by filing paper copies. See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121, May 1, 1998.

Comments filed through the ECFS can be sent as an electronic file via the Internet to <http://www.fcc.gov/e-file/ecfs.html>. Generally, only one copy of an electronic submission must be filed. In completing the transmittal screen, commenters should include their full name, U.S. Postal Service mailing address, and reference **ET Docket No. 05-213**. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions for e-mail comments, commenters should send an e-mail to ecfs@fcc.gov, and should include the following words in the body of the message, "get form <your e-mail address>." A sample form and directions will be sent in reply. Parties who choose to file by paper must file an original and four copies of each filing.

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). The Commission's contractor, Natek, Inc., 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 before 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 mail, Express mail, and Priority Mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

The full text of the waiver request 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.

By the Chief, Office of Engineering and Technology.
Office of Engineering and Technology contact: Bruce Romano at (202) 418-2124.