Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
DexCom, Inc.	)	
	)	
Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules	)	ET Docket No. 05-213
	)	
Expedited Action Requested	)	

REPLY OF DEXCOM, INC.

DexCom, Inc. ("DexCom"), by its attorneys, hereby submits its reply comments in support of its Request for Waiver. DexCom has provided substantial justification that expedited grant of its requested waiver of the Medical Implant Communications Service ("MICS") rules is necessary and would serve the public interest. The sole opposition, by Medtronic, Inc. ("Medtronic"), presents no basis for denying the relief requested by DexCom. Accordingly, the Commission should act expeditiously to grant DexCom a permanent waiver.

DISCUSSION

I. DEXCOM HAS MADE A SUFFICIENT SHOWING TO WARRANT A PERMANENT WAIVER OF THE MICS RULES.

The only issue presented by its waiver request is whether DexCom has provided sufficient justification to support a permanent waiver of the listen-before-transmit requirement of the MICS rules. DexCom has demonstrated that there is good cause for granting a waiver authorizing the operation of the DexCom blood glucose monitoring system with periodic scheduled transmissions. It is well established that the Commission may and should waive its rules if strict application of the rules would be

inconsistent with their underlying purpose and waiver of the rules would serve the public interest.[1] DexCom has satisfied this standard.

DexCom has shown that there is a substantial public interest in allowing its blood glucose monitoring system to be marketed as soon as possible. The purpose of the MICS rules is to make the therapeutic benefits of medical implant devices available to the public while avoiding harmful interference.[2] DexCom and the physicians and others, including the Juvenile Diabetes Research Foundation International, who have filed letters and comments in this proceeding have amply demonstrated the therapeutic benefits of the scheduled transmissions.[3] The record in this proceeding establishes that DexCom's system contributes significantly to public health and that regular, periodic transmissions are recognized by health care professionals as necessary to the health of their patients.

Moreover, the DexCom system can successfully share the MICS spectrum. Medtronic's claims of potential interference if Dexcom's waiver request is granted are speculative and lack technical support. The technical showings that DexCom has made directly refute Medtronic's claims. As the Commission has recognized, the fact that the MICS rules have a frequency monitoring requirement is not an indication *per se* that interference will occur in the absence of frequency monitoring.[4] Here, as in the Biotronik proceeding, the record demonstrates that grant of the waiver would not pose a risk of interference either to other users of the band or to users of DexCom's system.

---

[1] *See WAIT Radio v. FCC*, 418 F.2d 1153, 1159 (D.C. Cir. 1969), *cert. denied* 409 U.S. 1027 (1972).
[2] *See In the Matter of Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, 19 FCC Rcd 4208 (2004) ("Biotronik Waiver") (granting a similar waiver on the basis that Biotronik could not serve patient needs with a fully compliant MICS device).
[3] *See* Letters to Marlene H. Dortch, Secretary, Federal Communications Commission, from Lois Jovanovic, MD (April 28, 2005); from Steve Edelman, MD (May 3, 2005); from Sherwin L. Schwartz, MD (May 6, 2005); from Mark Johnson, Director of Business Development, Biotronik (July 12, 2005); from Peter Van Etten, President and CEO, Juvenile Diabetes Research Foundation International (July 26, 2005); and from Robert Tong, Senior Vice President, Medical and Wireless Products, AMI Semiconductor, Inc. (July 26, 2005).
[4] Biotronik Waiver, 19 FCC Rcd at 4213.

The short duration of the system's transmissions, its low power levels and its use of just one frequency ensure that DexCom's system can co-exist with other users in the MICS frequencies.[5]

Medtronic's interference claims are based on conclusory statements that cannot be squared with the facts.[6] For example, Medtronic asserts that a major medical event could be missed by other devices as a result of DexCom operating under the terms of its proposed waiver.[7] As AMI Semiconductor ("AMIS"), the manufacturer of the integrated circuits used in DexCom's system, explains:

> It is very unlikely, moreover, that the periodic transmission employed by the DexCom device would present any life threatening medical events to other MICS devices. The combination of very low duty cycle, transmission time, and range should pose little risk of interference.[8]

Accordingly, even if multiple MICS devices were present in a healthcare facility or a nursing home, the DexCom system is unlikely to cause harmful interference to another MICS device.

In terms of potential interference to federal users, there is no cause for concern. DexCom has been working with the National Weather Service/NOAA and the National Telecommunications and Information Administration ("NTIA") and has every

---

[5] For example, the rules allow transmissions of up to 5 seconds in duration, *see* 47 C.F.R. § 95.628(a)(4), but DexCom's system only transmits for 6-9 milliseconds, allowing sufficient room on the channel for other MICS transmissions.

[6] Medtronic's complaints notwithstanding, Medtronic Comments at 5, the fact that DexCom provided an approximate and not actual EIRP in its waiver request is immaterial to whether the impact of its devices can be evaluated; DexCom's system operates at just under 25 microwatts EIRP, is compliant with the power limitations of the MICS rules and it can be evaluated on this basis. As well, the EIRP calculation takes into account antenna gain. Medtronic cannot protest that it has insufficient information to access fully the interference impact of DexCom's system.

[7] *In the Matter of DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules*, Comments of Medtronic, Inc., ET Docket No. 05-213 (filed July 15, 2005) ("Medtronic Comments").

[8] *See* Letter to Marlene H. Dortch, Secretary, Federal Communications Commission, from Robert Tong, Senior Vice President, Medical and Wireless Products, AMI Semiconductor, Inc. (July 26, 2005) ("AMIS Letter").

indication that they are satisfied with the waiver request. Moreover, contrary to Medtronic's assertions, NTIA does not have a standing objection to "other similar non-compliant devices."[9] As the Commission explained in its Biotronik decision, NTIA withdrew its earlier objection to the Biotronik waiver.[10]

II. A WAIVER IS THE ONLY POSSIBLE WAY FOR THE PUBLIC TO RECEIVE THE BENEFITS FROM DEXCOM'S SYSTEM IN THE NEAR TERM.

According to Medtronic, DexCom must show that it can comply with the rules it is seeking to have waived.[11] There is no legal basis for this proposition, which effectively would eliminate the possibility of securing waivers. Indeed, this proposition was considered and rejected by the Commission in determining to grant the Biotronik waiver.[12] DexCom may be granted a waiver based on its showing that application of the rules would frustrate their purpose of providing appropriate spectrum for the operation of medical implant devices.

DexCom has no alternative but to seek a waiver of the listen-before-transmit requirements. It could not effectively serve patient needs with a fully compliant MICS device or with a device that operated using frequencies other than in the MICS band. DexCom's system could not offer the same therapeutic value if the company were required to change the system's design or operate it on a frequency outside of the MICS band.

A. It Is Impossible to Build A MICS-Compliant Device That Has the Full Utility of the DexCom System.

The technology does not exist for DexCom to build a blood glucose monitoring device that complies with MICS and provides diabetics with continuous blood glucose

---

[9] Medtronic Comments at 5-6.
[10] Biotronik Waiver, 19 FCC Rcd at 4212-4213.
[11] Medtronic Comments at 3.
[12] Biotronik Waiver, 19 FCC Rcd at 4212 (requiring only a showing that a party "cannot effectively serve patient needs with a fully compliant MICS device or a device that operates on other frequencies at the present time or in the near future.").

level information that is of significant therapeutic use. The bi-directional microchips suggested by Medtronic are larger than the chips used by DexCom and do not operate at as low a power level as DexCom's chips. Thus, the use of these "new" transceiver chips would not be feasible in the foreseeable future.[13]

Specifically, DexCom's system continuously monitors blood glucose levels and therefore imposes more demands on battery life than implantable medical devices that may be able to use a different type of transceiver chip.[14] This continuous monitoring feature provides substantial therapeutic benefit and means that, in order to meet the MICS listen-before-transmit requirements, the DexCom devices would have to be designed with much larger batteries to ensure sufficiently long battery life. AMI Semiconductor explains:

> Although AMIS, and other manufacturers, make integrated circuits that support listen before transmit (LBT), the availability of such circuits does not in itself signify that they are appropriate for every type of implantable device. For the DexCom technology, continuous monitoring of blood glucose levels imposes demands on the battery that are inconsistent with LBT. Enforcing full compliance with LBT for DexCom's implantable CGM device will reduce battery life significantly.[15]

For this reason, use of the chips suggested by Medtronic would cause Dexcom's devices to be too large to be used successfully in patients. Alternatively, it would require that

---

[13] DexCom disputes Medtronic's contention that state of the art transceivers are available for its immediate use. According to Zarlink, for example, its chips will not be available until late 2005. *See* Press Release, Zarlink Semiconductor, Zarlink Introduces the World's First Wireless Chip Designed Specifically for In-Body Communication Systems (May 31, 2005), *available at* www.zarlink.com.

[14] In contrast, Medtronic's blood glucose monitoring devices (CGMS and Guardian) do not provide "real-time" blood glucose measurements, but either store this information for later retrieval or sound an alarm only when blood glucose levels become dangerous. Thus, although these devices may be compliant with FCC regulations, they do not provide for the same level of patient benefit as DexCom's system.

[15] AMIS Letter at 1.

the devices be replaced much more often than other implantable devices, a prospect that would make the devices unacceptable to patients.[16]

B. The DexCom System Requires MICS Frequencies.

Simply because other manufacturers have products - with different functions – that comply with MICS rules does not mean that DexCom can or must do so as well. Requiring DexCom to alter its design or to use alternative frequency bands would cause technological hardships and international compatibility issues and require years of effort and additional costs. Such changes would unnecessarily delay the availability of medical implant devices that provide for significant improvements in therapy for millions of diabetic patients.

Additionally, DexCom cannot operate within the rules of a "Medical Data Service" ("MEDS") band proposed in Medtronic's petition for rulemaking. DexCom will comment on the merits of Medtronic's petition when and if the Commission seeks public comment on it. DexCom, however, can state even now that the "MEDS" rules that Medtronic proposes would impede the proper operation of its system. For example, the DexCom system employs a transmit duty cycle of less than 0.0035%, which is 28 times less than the duty cycle Medtronic proposes as being low enough to allow for reliable communications in the MEDS band. Moreover, MEDS power would be 100 times less than the power needed for DexCom's system. Reducing the output power of the system transmitter would severely restrict the range needed for proper

[16] Medtronic's comparison to the TheraSense device, Medtronic Comments at n. 20, or its own devices is inapposite. ThereSense operates on 315 MHz and Medtronic's devices on 418 MHz, both under Section 15.231 of the Commission's rules. 47 C.F.R. § 15.231. This rule significantly restricts the output power and duty cycle of devices that transmit periodically. Section 15.249, which governs operations on 916.5 MHz, has no duty cycle restrictions and allows output power as much as 30 times larger that what is allowed under MICS. *See* 47 C.F.R. § 15.429. Both environments would subject DexCom's system to substantial interference.

operation and would significantly increase the possibility of interference.[17] Further, it would be years before the suggested new MEDS band were approved by the FCC, assuming such approval ever would occur. Patients cannot wait that long.

Finally, the Commission has rejected Medtronic's suggestion that MICS devices that do not listen-before-transmit can operate successfully in other frequencies. It found in the Biotronik waiver decision that:

> [t]here does not appear to be suitable alternative spectrum for the very low power therapeutic devices. The existence of a few other medical transmit devices that operate at other frequencies on an unlicensed basis does not undercut this conclusion."[18]

It also determined that other frequency bands are sufficiently crowded so as to pose a serious risk of interference to low-powered medical devices.[19]

III. IT IS UNNECESSARY TO IMPOSE CONDITIONS OR LIMITS ON DEXCOM'S WAIVER.

No valid reasons have been presented to impose any conditions or limits on the waiver sought by DexCom. Notably, at least one other MICS user, Biotronik, supports the waiver without the imposition of any conditions.

Medtronic, without any technical basis, seeks to impose a myriad of severe conditions on the waiver based merely on unfounded statements that DexCom's system will cause interference to other MICS devices. Contrary to Medtronic claims, it is not proposing conditions "consistent" with the Biotronik waiver. For example, the Commission required Biotronik to give notice to medical professionals who implant the devices only of possible interference from METAIDS radiosondes and did not require the giving of notice of all conditions placed on the equipment, as Medtronic suggests

---

[17] DexCom's system requires a link budget configuration that allows a patient to, for example, move around, be up to 5 feet away from the receiver to take a shower and lie on the sensor while asleep.
[18] Biotronik Waiver, 19 FCC Rcd at 4213.
[19] *Id.*

DexCom must do.[20] Furthermore, this condition was only imposed because of a request from NTIA. In the present instance, NTIA has not requested that conditions be placed on the DexCom waiver, and there is no sound reason to require DexCom to warn physicians that its devices will cause interference when there is no evidence that this likely would occur. The Commission should reject the suggested conditions.

Medtronic also suggests that DexCom's Short Term Sensor ("STS") should not be allowed to operate as an "implant" under the MICS rules.[21] There is no basis for this suggestion. The MICS rules define Medical Implant Devices as those "placed inside the human body for the purpose of performing diagnostic or therapeutic functions."[22] The STS, like other MICS devices, is implanted in the body, and the transmitter remains whenever the sensor is changed. The STS, therefore, falls within the definition, and is an allowable device for MICS operations.

---

[20] Biotronik Waiver, 19 FCC Rcd at 4215.
[21] Medtronic Comments at 9.
[22] 47 C.F.R. Appendix 1, Subpart E, Part 95 (emphasis added).

CONCLUSION

DexCom's requested waiver should be granted. Medtronic seeks to cast DexCom's system out of the MICS altogether or have it redesign its system to comply with MICS rules. Neither option is feasible for DexCom. The Commission should act expeditiously to grant DexCom a permanent waiver of the listen-before-transmit requirement of the MICS rules.

Respectfully submitted,

DEXCOM, INC.

Henry Goldberg
Laura Stefani
GOLDBERG, GODLES, WIENER & WRIGHT
1229 Nineteenth Street, N.W.
Washington, D.C. 20036
(202) 429-4900
Its Attorneys

August 1, 2005

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Reply of DexCom, Inc. was sent by first-class mail, postage prepaid, this 1st day of August, 2005, to the following:

Robert L. Pettit
David E. Hilliard
John W. Kuzin
Wiley, Rein & Fielding, L.L.P.
1776 K St., NW
Washington, DC 20006

Bruce Romano
Office of Engineering and Technology
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Mark Johnson
Biotronik, Inc.
6024 Jean Rd. Bldg. B
Lake Oswego, OR 97002

/s/ Candace Gentry
Candace Gentry