Before the
Federal Communications Commission
Washington, D.C. 20554

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

ORDER

Adopted: January 12, 2006 **Released: January 18, 2006**

By the Commission:

I. INTRODUCTION

1. By this Order, we grant a request for waiver filed by DexCom, Inc.,[1] authorizing it to build and market its blood glucose monitoring system to operate in the Medical Implant Communications Service (MICS) band.[2] This waiver is granted for a period of three years, or until such time as the Commission amends its rules related to such devices to obviate the need for a waiver or to specify rules with which devices of this kind will be required to comply.

2. The DexCom STS (short-term) and LTS (long-term) blood glucose monitoring sensors are devices implanted into the body that combine a monitor with a low-power transmitter to provide frequent, periodic information regarding blood glucose levels. These monitor readings are transmitted to a receiver worn by a diabetic patient, so that the patient can continuously monitor his/her blood glucose level and take nutrition or medication (insulin) as necessary to maintain an appropriate glucose level in the blood. They can also send an alarm to the wearer when the blood glucose level falls outside acceptable levels. The devices operate on a single channel, and do not have a "listen before talk" (LBT) capability nor are they frequency agile, as required by the MICS rules.[3] Consequently, DexCom requests a waiver of these rules to permit it to manufacture and market, and for medical professionals to prescribe and diabetic patients to use, the STS and LTS as currently configured.

3. Opposition was filed by Medtronic, Inc. (Medtronic), the developer of a variety of medical implant devices, including implanted monitoring and communications devices for cardiac patients that comply fully with the MICS rules.[4] Comments supporting DexCom's request were filed by the Juvenile Diabetes Research Foundation (JDRF); Biotronik, a maker of other implantable medical

[1] Public Notice, June 15, 2005, DA 05-1670.

[2] MICS operates at 402-405 MHz, and is governed by Part 95, Subpart I of the Commission's rules (47 C.F.R §§ 95.1201ff; also 47 C.F.R. § 95.628).

[3] 47 C.F.R. § 95.1211.

[4] Meditronic also makes insulin pumps and a monitor for diabetics that communicate on non-MICS frequencies.

devices with transmitters; and AMI Semiconductors, Inc. (AMI), a provider of integrated circuits to the medical industry.

II. BACKGROUND

4. In 1999, the Commission established the MICS rules to allow the operation of radio transmitters that support 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.[5] The Commission determined that the 402-405 MHz band is particularly well suited for this service, due to the signal propagation characteristics in the human body, the relative dearth of other users of the band, the compatibility of the MICS service with the incumbent users of the band, and its use internationally for this purpose.[6] To avoid harming other users of the frequency band, MICS was provided a secondary allocation. The 402-405 MHz band was, and remains, allocated on a primary basis to Federal Government uses, including Meteorological Aids Service (Metaids), the Meteorological Satellite Service, and the Earth Exploration Satellite Service.[7] The Commission adopted technical rules for the MICS specifically designed to protect these incumbent Federal services, as well as to ensure compatibility among multiple MICS devices and users.[8] These rules establish a channel bandwidth of 300 kHz for this service within the allotted bandwidth,[9] provide for frequency sharing and cooperation in the selection and use of channels,[10] and establish specific guidelines for frequency monitoring prior to transmission by implant programmer/control transmitters.[11] [12] Given these protections, the National Telecommunications and Information Administration (NTIA), representing the incumbent Federal user entitled to exclusive use of this band, interposed no objection to this allocation.[13]

5. In 2003, the Commission found that another implanted medical device (a cardiac pacemaker with a transmitter for monitoring data concerning the heart) that operates similarly to the subject devices – at very low power with periodic, brief transmissions in the MICS band, lacking a listen-before-talk function and frequency agility – did not comply with the Commission's rules when sending

[5] *Report and Order* in WT Docket No. 99-66 (Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band) ("*MICS Order*"), 14 FCC Rcd, 21040 (1999).

[6] *Id.* at 21042-43.

[7] In this band, Metaids currently operates radiosondes, which are automatic transmitters, usually carried on an aircraft, free balloon, kite, or parachute, which transmit meteorological data during their journey through the atmosphere. (See 47 C.F.R. § 2.1.)

[8] *Id.* at 21046.

[9] 47 C.F.R. § 95.628(c), (d).

[10] 47 C.F.R. § 95.1211.

[11] 47 C.F.R. § 95.625(a).

[12] The Commission also provided that a MICS device could transmit without prior frequency monitoring, pursuant to a non-radio frequency actuation signal generated by a device external to the body (manual activation) (47 C.F.R. § 95.1209(b)), or in response to a medical implant event (47 C.F.R. §§ 95.628(b), 95.1209(b)). These functions are not the subject of the instant waiver request.

[13] NTIA is responsible for managing the Government portion of the Table of Frequency Allocations. In bands shared between Federal and non-Federal Government services, the Commission and NTIA operate under a long-standing coordination agreement. *See Manual of Regulations and Procedures for Federal Radio Frequency Management*, May 2005 Revision, Sec. 2.4.1.

regular, pre-programmed transmissions.[14] Subsequently, however, the Commission granted a temporary waiver for this device, finding that the device could not be made to comply with the MICS rules and still effectively serve patients at that time or in the near future, and that the minimal risk of harmful interference to or from the device was outweighed by the significant medical benefits that the device could immediately provide with existing technology.[15]

6. On July 15, 2005, Medtronic filed a Petition for Rulemaking proposing that a new Medical Data Service (MEDS) be established to operate on a secondary basis on spectrum adjacent to the MICS spectrum, to accommodate simple implanted and body-worn medical devices that are transmit-only and are not frequency agile. The Commission has issued a public notice seeking comment on that proposal.[16]

III. PLEADINGS

7. DexCom states that diabetes is a serious and costly health problem in the United States and worldwide. It contends that maintaining the proper blood glucose level is a critical element in controlling diabetes, and that a number of factors, anticipated and unanticipated, can affect blood glucose, so that constant monitoring is a necessary prerequisite for proper maintenance. It notes that monitoring is currently performed by a patient sticking his/her finger to draw a small amount of blood for testing, and asserts that this method is inconvenient, painful, and difficult to conduct and interpret properly. DexCom submits there is a great public need for implantable blood glucose sensors which can provide continuous, reliable blood glucose information to help each patient monitor his/her condition, and manage his/her diet, activity, and medication accordingly.

8. DexCom states that the STS and LTS[17] are designed to provide this continuous monitoring function. These implant devices include sensors that obtain blood glucose measurements and transmit them every five minutes to a receiver carried by the patient. A patient can, at any time, access information on his/her current blood glucose level and a chart of recent levels, to determine not only the current level but also how well the blood glucose level is being maintained. In addition, an alarm will sound with each periodic transmission when blood glucose becomes too high or too low, and repeat with each subsequent periodic transmission until the condition is corrected. DexCom claims that clinical studies show that its monitoring system increases the amount of time that a patient spends at his/her target blood glucose level by 88%.

9. DexCom asserts that there is no realistic chance of interference from or to the DexCom STS and LTS devices. It states that the devices operate at very low power levels, peaking at approximately -20dBm conducted, for an operating range of approximately five feet, and that they transmit on a single frequency and for only 6-9 milliseconds every five minutes. Accordingly, DexCom argues, there is virtually no chance of interference to other MICS devices. In addition, DexCom states that its system includes cyclic redundancy and unique identification codes, and the receiver is on only

[14] *In re Biotronik, Inc.* (*Philos MO&O*), 18 FCC Rcd. 3027 (2003). This decision affirmed on review the earlier action of the Office of Engineering and Technology (OET) that found that a regular periodic transmission violated the MICS rules.

[15] *In re Biotronik, Inc.* (*Biotronik Order*), 19 FCC Rcd. 4208 (2004). Medtronic opposed the earlier grant of equipment authorization and the request for waiver for the Biotronik Philos DR-T, on the basis that the periodic operation of the device without LBT functionality violates the MICS rules.

[16] Public Notice, August 24, 2005, Report No. 2725 (RM-11271).

[17] The STS uses a separate injectible probe that must be replaced every several days (the transmitter to which it is attached is more permanent); the LTS is a more complete monitoring unit that is fully implanted and remains for up to one year.

when the transmitter is transmitting, so that the integrity of the data in each transmission is ensured. It relates that if a transmission is blocked or missed, that event is included in the data available, and any such isolated failures will not compromise the utility of the trend data in a manner that would seriously affect the health or safety of the user.

10. DexCom claims that a rule waiver is necessary in order to provide this therapeutic tool to diabetics because technology does not exist to allow it to create an effective and practical system that incorporates LBT technology in these devices. According to DexCom, the unidirectional circuitry of the STS and LTS allows for a compact implant design which makes the device more readily implantable and more stable when implanted, as is critical for accurate reading of blood glucose levels. DexCom also states that this design, importantly, provides for a longer battery life, a critical factor for an implantable device.

11. Dexcom contends that a waiver would be consistent with the underlying purpose of the MICS rules, which it characterizes as making the diagnostic and therapeutic benefits of medical implant devices available to the public while avoiding harmful interference. In this regard, DexCom cites the prior grant of a waiver by the Commission to Biotronik for cardiac implant devices to operate using periodically scheduled transmissions without a LBT capability.[18] DexCom appends letters avowing the benefits of the STS and LTS devices from Dr. Lois Jovanovic of the the Sansum Diabetes Research Institute at the University of California at Santa Barbara, from Dr. Steve Edelman of the Veterans Affairs Medical Center at the University of California at San Diego, and from Dr. Sherwyn Schwartz, founder and medical director of the Diabetes and Glandular Disease Clinic of San Antonio, Texas. Each of these doctors describes his/her extensive experience and expertise in the fields of diabetes research and treatment, and attests to DexCom's claims as to the critical importance of regular blood glucose monitoring in controlling diabetes, and the desirability of a device such as the STS or LTS to accomplish this.

12. In support of the waiver request, the JDRF underscores the potential for positive impact that continuous glucose sensing technologies may have for diabetes patients, and asserts that a number of studies have shown that tighter glucose control can reduce the costly and debilitating complications associated with diabetes. Biotronik also asserts that the DexCom devices can improve the well being of millions of Americans, and agrees with DexCom that there is no potential for interference between the subject devices and other MICS users. It contends that a LBT function cannot be achieved without significant sacrifice to both battery longevity and the size of the device, and that each of these design considerations are critical for implantable medical devices. AMI also asserts that DexCom's implantable continuous glucose monitoring system provides significant medical benefits. As a provider of specific integrated circuits and standard products to the medical marketplace, AMI insists that such frequent monitoring imposes demands on the battery that are inconsistent with a LBT protocol. A larger battery or more frequent surgeries, it surmises, will reduce the number of patients that will use such a device. It, too, concludes that the combination of low duty cycle, transmission time, and range should pose little risk of interference.

13. Medtronic opposes the waiver request, contending that a waiver is unnecessary, as other spectrum is available for this device that would permit it to operate within the Commission's rules. It also claims that other medical device manufacturers are developing products that comply with the rules, contrary to DexCom's claim that a rule waiver is necessary to design and manufacture suitable medical implant devices. It submits that ultra-low power MICS transceiver chips are now available from a number of sources, and that compliance with the LBT requirement is fully within the state of the art. It contends that grant of this waiver would compromise the integrity of the MICS service as more and more patients rely on intelligent medical implants to convey time-sensitive information. It also asserts that

[18] *Biotronik Order*, *supra*.

many international regulatory bodies call for smart radio technology for medical implant communications devices operating at 402-405 MHz, and that LBT is a cornerstone of the MICS. Medtronic also complains that DexCom's failure to disclose key RF system operating parameters or to provide a complete description of its sensor systems makes it impossible to assess fully the interference impact of the STS and LTS on other low-power medical devices, and asserts that the DexCom device would be subject to receiving interference. Medtronic also argues that the transmitter portion of the devices rests on top of the skin, and thus is not within the purview of the MICS rules. It urges the Commission, if it does grant a waiver, to require that DexCom use spectrum directly adjacent to the MICS spectrum, and proposes several conditions. Specifically, it asks that we limit the waiver to two years; that we apply it only to subcutaneous and transcutaneous equipment and exclude equipment that is entirely external to the body; that we limit operation to non-life-critical, non-emergency communications; that we require that medical professionals and patients be given prior notice of the potential of interference from Metaids radiosondes along with instruction on how to mitigate interference; and that we require system administrators to give medical professionals and patients notice of each of the conditions placed on the DexCom equipment. Medtronic notes that it has filed a petition for rulemaking to establish the Medical Data Service (MEDS) at 401-402 and 405-406 MHz for just such devices.[19]

IV. DISCUSSION

14. We find that a temporary waiver for the DexCom STS and LTS to operate as currently designed is warranted. There is good cause for granting this waiver, and it is in the public interest to do so.[20] To deny the waiver would frustrate the underlying purpose of the rules and DexCom and the diabetic patients its devices will serve have no reasonable alternative to obtain the important benefits afforded by the DexCom devices at this time.[21] The periodic/automatic transmissions of the STS and LTS will assist diabetics in maintaining their blood glucose levels, a very significant therapeutic benefit that was a basis for the establishment of the MICS rules, without posing an undue potential for interference.[22] This waiver is granted for three years, or until completion of any rule making the Commission may undertake, whichever is later. If rules are adopted with which the STS and LTS comply, the waiver will become moot. If rules are adopted that would require modifications to the STS and LTS, such as a change in power or frequency, DexCom will have one year from the effective date of such rules to bring its devices into compliance. In any event, any devices implanted pursuant to the instant waiver may continue operating until the end of their useful life.

15. The significant medical value of these devices as presently constituted for current diabetic patients is a compelling factor in our consideration. The substantial public interest in making a blood glucose monitoring system available is uncontested. According to the un-refuted statements of DexCom and its supporters in this waiver request, close to 20 million Americans and over 170 million people worldwide suffer from diabetes, and it is the fifth-leading cause of death by disease in the United States. Diabetes and complications from diabetes, including heart disease, stroke, loss of eyesight, loss of kidney function, and amputation of limbs, is presently estimated at $132 billion per year, including $90 billion in direct medical care costs. While there is no known cure for diabetes, a critical goal of medical care is to manage patients' blood sugar levels to control the disease. Regular monitoring is, in turn, a critical element of achieving this. Unfortunately, two-thirds of Type 2 diabetics[23] in America do not have

[19] See para. 6, *supra*.

[20] *See WAIT Radio v. FCC*, 459 F.2d 1203, 1207 (D.C. Cir. 1972).

[21] *See* 47 C.F.R. § 1.925.

[22] *MICS Order*, *supra* at 21040.

[23] Type 2 diabetes is the most common form of diabetes, in which either the body does not produce enough insulin or the cells ignore the insulin. Without insulin, the body is unable to use sugar, which is the basic fuel for the cells (continued....)

adequate control of their blood glucose levels. The importance of regular monitoring and maintenance is attested to by several experts in the field, and by several studies referred to by DexCom. In addition, DexCom has submitted data derived from clinical trials which compare the blood sugar levels of a patient using the traditional, and less frequent, "finger stick" method with the continuous data available from the DexCom system; this data demonstrate a dramatic improvement with continuous monitoring. We also take cognizance of DexCom's statement that the Federal Drug Administration is expediting its review of the devices in view of the health benefits they promise.

16. DexCom has also demonstrated that there is little risk of harmful interference caused by or occurring to the devices. While Medtronic charges that it does not have complete information regarding the RF characteristics of the devices, such as their exact power level, so as to assess their potential to interfere with MICS devices, we find the information available is sufficient to make this determination when considered in the light least favorable to DexCom. The STS and LTS will operate on only one frequency (402.142 MHz +/-40 kHz), occupying only 120 kHz of bandwidth, at a power level less than that permitted in the MICS band (-20dBm conducted),[24] and for only 6-9 milliseconds every five minutes. This combination of bandwidth, power, and duration make the likelihood of causing interference virtually nil. Given the proximity of the receiver to the transmitter, it is also highly unlikely that another MICS device will be sufficiently close to cause interference to a DexCom device while attempting to transmit at the same moment and on the same frequency as a DexCom device. The likelihood of interference to a DexCom receiver that would obstruct its basic function is even further remote, given the frequency of data transmissions and the non-critical nature of an individual transmission. If an undesired signal is received, the data will not be corrupted, but simply blocked from reception. If a transmission is not received due to interference, the loss of that data point, one of 288 per day, is not critical to the overall monitoring function provided by the monitor.[25] If that particular reading or datum warrants an alarm, the alarm will be resent with each subsequent periodic transmission until the patient's blood glucose level returns to an acceptable level, and while prompt response by the patient is desirable, a delay of minutes is not critical. We note, too, that the National Telecommunications and Information Administration (NTIA), which represents the primary, licensed, users of this band and is concerned with any possible negative effects of its operation, has raised no objection to this waiver.

17. DexCom has also shown that a waiver of the MICS rules is necessary for its device to function effectively. The unidirectional circuitry of the device allows for a compact and lightweight design that will remain in place for accurate sensing, with a relatively long life. Moreover, keeping down the cost of the system will make it accessible to more users. While Medtronic asserts that compliant technology exists, the examples it provides are either not presently available or do not appear suitable for the device that DexCom has developed. The existence of a few other medical transmit devices that operate at other frequencies on an unlicensed basis does not undercut this conclusion. While there is other spectrum in which unlicensed devices can operate, the spectrum specifically suggested by Medtronic[26] has restrictions that are inappropriate for the subject devices or are sufficiently congested to pose a risk that the very low powered transmissions of the subject devices would be at greater risk of receiving interference; moreover, they would have no interference protection from the plethora of other devices operating in those bands. Neither do we see a need to require DexCom to redesign its equipment

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in the body, and insulin takes the sugar from the blood into the cells. When sugar (glucose) builds up in the blood instead of going into cells, it can cause two problems: cells are immediately starved for energy, and over time, high blood glucose levels damage your eyes, kidneys, nerves or heart and lead to deterioration of the feet and legs.

[24] 47 C.F.R. § 95.639 permits a maximum EIRP of 25 microwatts.

[25] We note that FDA will require that patients continue to "finger prick," to ensure the availability of blood glucose information in the event of a malfunction of the device.

[26] Medtronic cites devices that operate under Part 15 of the FCC's rules at 315 MHz, 418 MHz, and 916.5 MHz.

to use alternative spectrum adjacent to the MICS spectrum, as suggested by Medtronic. Such a change would not obviate the need for a waiver and, as indicated above, we do not anticipate a realistic likelihood of interference, at least in the timeframe encompassed by this waiver. Moreover, given the potential for a rulemaking proceeding addressing medical telemetry devices and the spectrum at issue, it would be premature to move these devices off the frequency currently designated for medical implant communications.

18. Medtronic's argument that DexCom cannot invoke the MICS rules because the transmitter for the STS lies above the skin is unavailing. Section 95.1201 of our rules provides that "[a] person is permitted to operate medical implant transmitters connected to medical implant devices that have been implanted in that person…."[27] The phrase "that have been implanted" can modify "medical implant devices" or it can modify "medical implant transmitters connected to medical implant devices." The text of the *MICS Order* is not conclusive in this regard. We do note that the term "medical implant transmitter" is defined as "[a] MICS transmitter that operates or is designed to operate within a human body…" in the appendix to subpart E of Part 95.[28] In any event, DexCom is seeking waiver of the MICS rules, not to invoke the MICS rules, so that a determination of this issue is not required in order to grant the waiver request. We will clarify this issue in any future proceeding on medical implant devices.

19. Finally, most of the conditions sought by Medtronic are variously inappropriate or unnecessary. We reject Medtronic's request that we restrict the waiver to subcutaneous and transcutaneous transmitters for the reasons indicated above. We also reject its request for a two-year limit. Instead, we are making the waiver dependent on the timing and outcome of any relevant rule making we may conclude, with a minimum of three years as a reasonable timeframe for successfully marketing and implementing use of the subject devices in their current configuration. There is no evidence that the MICS band would become so congested in that time that the STS and LTS would pose an undue interference risk if the current rules are maintained. Moreover, this period will provide a better picture of the utility and interference potential of these devices should a dispositive rule making not conclude in the interim and a subsequent waiver be presented for consideration. Its proposed limitation regarding the devices' operational characteristics are necessarily observed in granting this waiver for the specific subject devices. Proposed warnings regarding potential interference from radiosondes are largely unnecessary, given the insignificance of such interference when it might occur. The other conditions we do impose (below) do not comprise pertinent information for medical professionals or patients using the subject devices.

20. We recognize here, as we did in granting the Biotronik waiver, that this waiver request and our action herein may presage a need or a reasonable desire for additional medical implant devices that would operate at variance with the current MICS rules.[29] As noted above, we have very recently accepted comment on just such a proposal by Medtronic, and the waiver granted herein is subject, after a prescribed transition period to modification based on any rules we may adopt.

21. For the above reasons, we will grant this waiver for a period of three years, or until one year after completion of any rule making the Commission may undertake regarding medical implant devices, whichever is later. Additionally, we will condition the continued implantation of the devices covered by this waiver on their non-interference with other MICS devices and with the primary users of this spectrum. Should a pattern of interference develop that is traceable to devices operating pursuant to

[27] 47 C.F.R. § 95.1201.

[28] See Appendix 1 to Subpart E of Part 95 – Glossary of Terms.

[29] *Biotronik Order, supra* at 4214.

this waiver, we will rescind the waiver to prohibit the implantation of additional devices.[30] This period of time should provide an adequate window for the successful manufacture and utilization of the subject devices while we contemplate changes to the medical implant rules. Also, during this period, advances in technology may improve the operability and availability of listen-before-talk implantable devices, obviating the need for a waiver for future devices.

V. ORDERING CLAUSES

22. Accordingly, pursuant to Section 1.925 of the Commission's rules (47 C.F.R. § 1.925), DexCom's petition for waiver of the MICS rules IS GRANTED for the manufacture and use of the STS and LTS blood glucose monitoring systems, as described in this Order, subject to the following conditions:

Devices authorized by this waiver will:

(a) Occupy no more than 120 kHz of bandwidth at 402.142 MHz +/- 40 kHz;

(b) Provide transmissions that do not exceed 10 milliseconds each;

(c) Employ a duty cycle that does not exceed one transmission every five minutes;

This waiver does not relieve DexCom of the requirement to avoid interference to other MICS devices and to the licensed primary users of this band.

This waiver does not provide the subject devices with protection of transmissions by authorized users of the band.

This waiver expires three years from the release date of this Order or until one year after completion of any rule making the Commission may undertake, whichever is later. After that time, LTS devices implanted pursuant to this waiver may continue to operate, but use of STS devices under this waiver must cease and no additional LTS devices can be implanted in patients pursuant to this waiver.

FEDERAL COMMUNICATIONS COMMISSION

Marlene H. Dortch
Secretary

[30] We would not, of course, require the removal of LTS devices appropriately implanted pursuant to this waiver; we would require discontinuation of use of STS devices.