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Federal Communications Commission  
Office of the Secretary

ET Doc. No. 05-213

March 8, 2013

By Electronic Mail and  
First Class Mail

Julius Knapp, Chief  
Office of Engineering and Technology  
Federal Communications Commission  
445 12<sup>th</sup> Street, SW  
Washington, D.C. 20554

Re: **Waiver Grant to DexCom, Inc.**  
**Confirmation of Warranty Replacement Abilities**

Dear Mr. Knapp:

We are writing with regard to the grant by the Federal Communications Commission ("Commission" or "FCC") of a waiver to DexCom, Inc. ("DexCom"), and in particular the ability of DexCom to provide warranty replacement after the expiration of the waiver.

As you know, in 2006 the Commission granted DexCom a waiver of the MedRadio (then, MICS) rules to allow its continuous glucose monitoring ("CGM") devices to operate without employing a listen-before-transmit ("LBT") protocol.<sup>1</sup> Subsequently, in the Report and Order establishing the MedRadio Service, the Commission extended the term of this waiver until August 13, 2013, four years from the effective date of the order.<sup>2</sup>

<sup>1</sup> *In the Matter of DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules*, Order, 21 FCC Rcd 875 (2006) ("DexCom Waiver")

<sup>2</sup> *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 Radiocommunication Service at 401-402 and 405-406 MHz; DexCom, Inc., Request for Waiver of the Frequency Monitoring*

footnote cont'd on next page /

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In October 2012, DexCom released its new Gen 4 system, allowing it stop marketing its Seven Plus system (which operates in the MedRadio band) and to transition to the 2.4 GHz band.<sup>3</sup> However, DexCom's warranty agreements provide that it will supply a replacement transmitter in the event of a device failure. Thus, under the terms of its warranty agreements, for the one year period after the sale of its last Seven Plus system, through December 31, 2013, DexCom must have the ability to replace any failed Seven Plus transmitter with another Seven Plus transmitter, one that would operate in the MedRadio band under the terms of the waiver.<sup>4</sup> DexCom will not be able to use its Gen 4 device transmitters for warranty replacement of Seven Plus transmitters as the Gen 4 devices will operate in the 2.4 GHz frequency band, requiring the replacement of the entire system and not just the transmitter.

It is our understanding that DexCom may provide this warranty coverage under the DexCom waiver; accordingly, DexCom seeks written confirmation of this conclusion at your earliest convenience.

Sincerely,



Henry Goldberg  
Laura Stefani  
*Counsel for DexCom, Inc.*

cc: Bruce Romano

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*Requirements of the Medical Implant Communications Service Rules; Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Report and Order at ¶ 73, 24 FCC Rcd 3474 (2009) ("MedRadio Order").*

<sup>3</sup> DexCom is awaiting FDA approval for multi-patient use of the Gen 4 device, however, and is seeking a one-year extension of the waiver grant for multi-patient use of its MedRadio system.

<sup>4</sup> DexCom estimates that at most 500 units would need to be replaced during this time period.