Mr. Terry G. Mahn
Fish & Richardson, P.C.
1000 Maine Avenue S.W.
Suite 1000
Washington, DC 20024

Subject: Request for Modification of Waiver Granted to Kyma Medical Technologies Ltd. DA 16-1009

Dear Mr. Mahn:

In response to your letter dated May 17, 2019, on behalf of your client Zoll Medical Israel Ltd. (Zoll), successor in interest to Kyma Medical Technologies Ltd. (Kyma), the Office of Engineering and Technology (OET) is granting your request to modify an existing waiver to accommodate the more frequent transmissions during the operation of Zoll's ultra-wideband (UWB) medical imaging device.[1]

On September 6, 2016. OET granted a waiver of Sections 15.31(c), 15.503(d), 15.513(a), and 15.521(d) of the UWB rules to allow the certification and marketing of the uCor, a medical device designed to monitor patients suffering from congestive heart failure.[2] These rules set forth the method for measuring radio frequency emissions, define the bandwidth requirement for a UWB transmitter, and state the frequency range in which UWB medical imaging systems must be contained. The waiver also established conditions specific to the uCor, such as a maximum time the device could dwell on any frequency, limitations how and when the device could be used, and a restriction on operation (i.e. duty cycle) to 8 times per day with each use limited to a maximum of 60 seconds.[3]

You state that Zoll has made a minor modification of the uCor's operations to increase the maximum number of transmissions from 8 times per day to 100 times per day. Generating a greater number of patient readings, which will be spread over the course of a day, will permit the uCor to improve patient outcomes. You further state that "[i]n all other respects, the modified device is technically and operationally identical to the waivered device."[4] Accordingly, Zoll only seeks a modification of the waiver condition dealing with the daily duty cycle and warrants

[1] Letter from Terry G. Mahn, Counsel to Zoll Medical Israel Ltd., to Marlene H. Dortch, Secretary, Federal Communications Commission (May 17, 2019) (filed in INBOX-PART 15 in the Commission's Electronic Comment Filing System) (Zoll Waiver Modification Letter). This letter corrected and replaced an earlier submission made on behalf of Zoll.

[2] *Kyma Medical Technologies Ltd. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra Wideband Devices*, Order, 31 FCC Rcd 9705 (OET 2016) (Kyma Order).

[3] *Id.* at 2-3.

[4] Zoll Waiver Modification Letter at 3.

that the new uCor device does not require any other changes for the conditions in the Kyma Order.[5]

We are authorized to grant a waiver under Section 1.3 of the Commission's rules if the petitioner demonstrates good cause for such action.[6] Good cause, in turn, may be found and a waiver granted "where particular facts would make strict compliance inconsistent with the public interest."[7] To make this public interest determination, the waiver cannot undermine the purposes of the rule, and there must be a stronger public interest benefit in granting the waiver than in applying the rule.[8]

We find that under Zoll's requested modification, the waiver standard will continue to be satisfied. Increasing the number of times the device operates per day is an evolutionary design change that will be beneficial to patients and health care professionals. From a technical perspective, this is a minor alteration in that it does not require changes to any other technical or operational conditions included in the existing waiver – conditions that we previously determined were sufficient to protect other spectrum users.[9] Moreover, the uCor will continue to be used as specialized medical device that is only employed by healthcare professionals while patients are being actively monitored. Accordingly, we find that the continuing waiver conditions and nature of the device both ensure that use of the modified uCor model presents no new risk of causing harmful interference to communications services.

To give effect to our decision, we revise the eleventh condition of the existing waiver to read as follows: "The uCor device shall not operate more than 100 times per day, each time for a duration not to exceed 60 seconds." All other conditions associated with the waiver continue to apply without alteration.[10]

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[5] *Id.* at 5.

[6] 47 C.F.R. § 1.3. *See also ICO Global Communications (Holdings) Limited v. FCC*, 428 F.3d 264 (D.C. Cir. 2005); *Northeast Cellular Telephone Co. v. FCC*, 897 F.2d 1164 (D.C. Cir. 1990); *WAIT Radio v. FCC*, 418 F.2d 1153 (D.C. Cir. 1969).

[7] *Northeast Cellular*, 897 F.2d at 1166; *see also ICO Global Communications*, 428 F.3d at 269 (quoting *Northeast Cellular*); *WAIT Radio*, 418 F.2d at 1157-59.

[8] *See, e.g.*, *WAIT Radio*, 418 F.2d at 1157 and *Northeast Cellular*, 897 F.2d at 1166.

[9] These include, for example, limiting the dwell time on any one frequency to no more than 100 microseconds in any 20 millisecond period, and limiting the operations of the device to body imaging measurement functions, and requiring the device to cease transmissions when not in contact with the human body. Kyma Order at 9-10.

[10] We will place a copy of this letter in ET Docket No. 15-199, the docket associated with the Kyma Order.

Accordingly, pursuant to authority delegated in Sections 0.31 and 0.241 AND 1.3 of the Commission's rules, 47 C.F.R §§ 0.31, 0.241, and 1.3, and Sections 4(i), 302, 303(e), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C §§ 154(i), 302, 303(e), and 303(r), IT IS ORDERED that the waiver issued to Kyma by Order dated September 6, 2016, is hereby modified as described above effective upon release of this Order.

FEDERAL COMMUNICATIONS COMMISSION

Julius Knapp
Chief
Office of Engineering and Technology