



PUBLIC NOTICE

Federal Communications Commission
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**OFFICE OF ENGINEERING AND TECHNOLOGY DECLARES THE KYMA
MEDICAL TECHNOLOGIES LTD REQUEST FOR WAIVER OF PART 15 ULTRA-
WIDEBAND RULES FOR A MEDICAL IMAGING SYSTEM TO BE A “PERMIT-BUT-
DISCLOSE” PROCEEDING FOR *EX PARTE* PURPOSES AND REQUESTS
COMMENT**

ET Docket No. 15-119

Comment Date: June 19, 2015
Reply Comment Date: July 6, 2015

On May 14, 2015, Kyma Medical Technologies Ltd (Kyma) filed a request for waiver of Sections 15.503(d), 15.513(a), 15.521(d), and 15.525 of the Commission’s rules to allow the marketing and operation of its stepped frequency ultra-wideband (UWB) medical imaging and diagnostic device known as uCor 3.0 (uCor). Kyma states that the uCor device is an advanced RF diagnostic device that non-invasively monitors lung fluid levels and trends to treat patients with congestive heart failure. The device employs a very low power RF signal that is directed into the patient’s torso via a small transmitter that is temporarily attached to the skin. Signals from the uCor propagate through the chest and lungs and reflect back from the heart. Data collected by the uCor is transferred via standard wireless interface over the internet and on to a data center where it can be analyzed by a healthcare provider.

Section 15.503 (d) of the Commission’s rules defines an ultra-wideband transmitter as an intentional radiator that, at any point in time, has a fractional bandwidth equal to or greater than 0.20 or has a UWB bandwidth equal to or greater than 500 MHz, regardless of the fractional bandwidth. Kyma states that its uCor device would not satisfy this definition since each frequency step is less than 500 MHz in bandwidth “at any point in time” even though the total bandwidth needed for optimal performance exceeds 500 MHz.

Section 15.513 requires that the UWB bandwidth of a medical imaging system be contained between 3100 MHz and 10,600 MHz. Kyma states that the uCor device must operate between 530 MHz and 2.105 GHz to both penetrate the human body and generate precise image information.

The testing procedures outlined in Section 15.521 (d) require that measurements for emissions above 960 MHz be made with an RMS average detector over a 1 MHz resolution bandwidth. The rule also requires that if pulse gating is employed where the transmitter is quiescent for intervals that are long compared to the nominal pulse repetition interval, measurements shall be made with the pulse train gated on. Kyma believes that if they are required to measure their emissions with the stepping function

stopped, that the peak emissions would need to be drastically reduced and this would force the their device to operate at reduced performance levels.

Section 15.525 requires that all devices certified under the UWB rules must coordinate the deployment of each device with federal agencies through NTIA. Kyma states that this is impractical for its patient-worn device and thus also requests a waiver of this rule.

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

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR §§ 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). See *Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998).

- Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: <http://fjallfoss.fcc.gov/ecfs2/>.
- Paper Filers: Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW, Room TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes 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, Express, and Priority mail must be addressed to 445 12th Street, SW, Washington DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

Parties should also send a copy of their filings to Aole Wilkins, Office of Engineering and Technology, Federal Communications Commission, Room 7-A201, 445 12th Street, S.W., Washington, D.C. 20554, or by e-mail to aole.wilkins@fcc.gov.

Documents in are available for public inspection and copying during business hours at the FCC Reference Information Center, Portals II, 445 12th Street, S.W., Room CY-A257, Washington, D.C. 20554.

Office of Engineering and Technology contact: Aole Wilkins at 202-418-2406.

By the Chief, Office of Engineering and Technology

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