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May 14, 2015

FILED: FCC ECFS

Marlene H. Dortch, Secretary
Federal Communications Commission
Office of the Secretary
445 12th Street S.W.
Washington, D.C. 20002

Re: In the Matter of Petition for Waiver of Sections 15.503(d), 15.513(a), 15.521(d) and 15.525 of the Commission's Rules.

Dear Ms. Dortch,

Enclosed please find a Petition for Waiver filed on behalf of Kyma Medical Technologies Ltd. If there are any questions regarding this filing, please contact the undersigned.

Very truly yours,

Jay S. Newman

Enclosures

cc (via email): Julius Knapp, Chief, OET
Bruce A. Romano. Associate Chief (Legal), OET
Mark Settle, Chief, Policy and Rules Division, OET
Edward Drocella, NTIA

Before the

Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)
	)
Kyma Medical Technologies Ltd	)
Waiver of Part 15 of the Commission's Rules	)
Applicable to Ultra-Wideband Devices	)

REQUEST FOR WAIVER

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TABLE OF CONTENTS

Page

Request For Waiver.....1

Summary.....2

I. The uCor Device Represents a Significant Advance in the Treatment of CHF Patients.....4

II. This Waiver Request Satisfies the Commission's General Standard for Granting Waivers and is Consistent with Recent UWB-Related Granted Waivers.....11

III. Consistent with Recent Precedent, Rule 15.503(d) Should be Waived to Permit a Fast, Stepped-Frequency Emitter Operating Over Approximately 1.6 GHz of Spectrum to Qualify as a UWB Device.....13

IV. Consistent with Recent Precedent, the UWB Test Procedures Should be Waived to Allow Average Measurements Above 960 MHz to be Made With the Stepping Function Active.....16

V. Rule 15.513(a) Should be Waived to Permit a Medical Imaging System to Operate Below 3.1 GHz.....19

A. UWB Medical Imaging Technology has not Developed Since the 2002 UWB Rules were Adopted.....20

B. The Commission Adopted 3.1 GHz as the Lower End of the Frequency Band for UWB Medical Imaging Devices to Address Potential (but Uncorroborated) Interference Concerns.....21

C. The Commission has Imposed Less Stringent Minimum Threshold Requirements on UWB Non-Medical Imaging Devices, Thereby Showing Flexibility and Allowing Operation of such Devices below 3.1 GHz.....24

D. Kyma's Medical Imaging Device should also be Permitted to Operate below 3.1 GHz because such Operations do not Raise Interference or Safety Risks.....28

E. Relaxing the Restraints of UWB Rules is Consistent with FCC's Previous Statements on UWB Operations.....29

VI. Rule 15.525 should be Waived or Relaxed as it applies to Kyma's uCor Device.....30

VII. Conclusion.....32

Attachment

Before the

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Washington, D.C. 20554

In the Matter of	)
	)
Kyma Medical Technologies Ltd	)
Waiver of Part 15 of the Commission's Rules	)
Applicable to Ultra-Wideband Devices	)

REQUEST FOR WAIVER

Kyma Medical Technologies Ltd ("Kyma"), through its counsel, hereby requests a limited waiver of the Commission's Part 15 rules and test procedures governing ultra-wideband ("UWB") medical imaging systems. Kyma intends to market a technologically advanced, stepped-frequency UWB medical imaging and diagnostic device known as uCor 3.0 ("uCor Device" or "uCor") to provide non-invasive monitoring and diagnosing of patients suffering from Congestive Heart Failure ("CHF").[1] However, because medical-grade RF imaging of lung and cardiac tissue requires the use of frequencies below 3.1 GHz, the uCor Device will need a waiver of Section 15.513(a). In addition, the uCor will require a waiver of Section 15.503(d) (UWB definition), Section 15.521(d) (compliance measurement procedures) and Section 15.525 (coordination requirement).

[1] As noted herein, the uCor device employs UWB radio frequency ("RF") to identify or detect fluid build-up in the lungs. As such, the uCor device meets the broad definition of a "medical imaging system" even though it is not designed to display images of the collected tissue data on a video monitor.

Summary

Although the uCor Device utilizes almost 1.6 GHz of bandwidth to perform its medical imaging functions, it does not squarely meet the definition of an UWB transmission device set forth in Section 15.503(d) of the Commission's rules because the "instantaneous bandwidth" during any frequency step is less than 500 MHz. However, the Commission recently waived this definitional requirement for a stepped-frequency ground penetrating radar ("GPR") device where it was demonstrated that emissions from the stepped-frequency device were functionally equivalent to a pulsed UWB GPR, and the risk of interference to other spectrum users would be no greater than that posed by a pulsed UWB GPR.[2]

In addition, the uCor Device requires that average emissions be measured for compliance with the stepping function "active" to achieve the RF energy levels required for the medical imaging of cardiac tissue. Although Commission test procedures generally require stepped-frequency devices to be measured with the stepping function inactive, the Commission has waived this procedure on several occasions upon a showing of good cause that such action would serve the public interest.[3]

Furthermore, the uCor Device must operate between 530 MHz and 2.105 GHz to both penetrate the human body and generate precise image information on lung fluid levels and trends that are indicative of medical complications in CHF patients. Although Section 15.513(a) of the

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[2] *See In the Matter of Curtiss-Wright Controls Inc. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices,* ET Docket No. 10-167, Order, 27 FCC Rcd 00234 (2012) ("*3d-Radar Waiver*").

[3] *See 3d-Radar Waiver* and *Petition for Waiver of the Part 15 UWB Regulations Filed by the Multi-band OFDM Alliance Special Interest Group,* ET Docket No. 04-352, Order, 20 FCC Rcd 5528 (2005) ("*MBOA-SIG Waiver*").

Commission's rules governing UWB medical imaging systems require that such systems operate between 3.1 GHz – 10.6 GHz, the Commission noted when it initially adopted the UWB rules in 2002, that this band of operation -- including the lower frequency limit – was designed to be extremely conservative. More specifically, the Commission indicated that it was open to adopt more flexible technical UWB standards as the agency gained more experience with UWB technology.[4]

Finally, Kyma seeks either a waiver or relaxation of the Commission's coordination requirements set forth in Section 15.525 for the uCor Device. The coordination requirement is an atavistic rule that was adopted at the time when UWB devices were first emerging, and was based on limited knowledge of this new technology and exaggerated concerns about the potential for harmful interference. Application of this burdensome rule to the uCor Device – a patient-worn device that is operated intermittently and, primarily, indoors -- is neither practical nor necessary given the extremely low risk of interference the device poses to other spectrum users.

As discussed more fully below, the public interest will be served by waiving the Commission's UWB rules as requested herein. Indeed, in the years since the UWB rules were adopted, not a single medical imaging device has been approved under Section 15.513. Thus, the current rules have served more as a barrier than an opportunity to the development of UWB medical imaging technologies -- clearly not what the Commission had intended when the rules were adopted. A

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[4] *In the Matter of Revision of Part 15 of the Commission's Rules Regarding Ultra-Wideband Transmission Systems,* First Report and Order, 17 FCC Rcd 7435 at ¶ 1 (2002) ("*2002 UWB First Report and Order*").

grant of this waiver, therefore, will be a significant step forward in promoting UWB imaging applications in the medical field.

I. The uCor Device Represents a Significant Advance in the Treatment of CHF Patients.

CHF is one of the most common cardiovascular diseases affecting approximately 6.6 million people in the United States alone.[5] Over the next year, 670,000 people will be newly diagnosed with CHF and about half will die from the condition within five years of diagnosis.[6] CHF inflicts a substantial cost burden on the U.S. healthcare system estimated at $39.2 billion, which is more than that of all cancers combined.[7]

One of the most severe manifestations of CHF is pulmonary congestion, a potentially fatal condition in which fluid builds up in the lungs and a leading cause of hospitalizations among heart failure patients. About $26 billion in health care spending can be attributed to heart failure hospitalizations, a significant percentage of which is due to soaring readmission rates which can be as high as 50% during the six months following a discharge.[8]

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[5] Veronique L. Roger et al., *Heart Disease and Stroke Statistics - 2012 Update: A Report from the American Heart Association*, Circulation, 125: e2-e220, e102 (2012) available at http://circ.ahajournals.org/content/125/1/e2.full.pdf+html.

[6] *Id.* at e103 and Alan S. Go et al., *Heart Disease and Stroke Statistics—2013 Update: a Report from the American Heart Association*, Circulation, 127: e6–e245, e202 (Table 19-1) (2013) available at http://circ.ahajournals.org/content/127/1/e6.full.pdf+html.

[7] Donald Lloyd-Jones et al., *Heart Disease and Stroke Statistics--2010 Update: a Report from the American Heart Association*, Circulation, 121: e46, e132 (Table 8-1) and e206 (Table 20-1) (Feb 23, 2010) available at http://circ.ahajournals.org/content/121/7/e46.full.pdf.

[8] Akshay S. Desai, MD, MPH and Lynne W. Stevenson, MD, *Rehospitalization for Heart Failure -- Predict or Prevent?*, Circulation, 126: 501-506, 501 (2012) available at http://circ.ahajournals.org/content/126/4/501.full.pdf+html.

If detected early in its onset, however, pulmonary congestion often can be treated at home by adjusting medications. Studies have concluded that readmissions for CHF could be prevented in at least 40 percent of cases if there was early detection.[9] Unfortunately, the majority of CHF monitoring solutions on the market still rely on traditional methods of daily body weight measurements and patient surveys both of which offer low prediction rates and suffer from poor patient compliance. Typically, CHF patients are required to continuously (and methodically) take and report weight measurements as a crude predictor of pulmonary congestion. Even if this "quill and ink" monitoring is done properly (and very often it is not) such measurements and surveys do not necessarily confirm the existence of pulmonary congestion. Rather, they simply identify the symptoms of possible existence of pulmonary congestion.

The current gold standard and Class I indication[10] for heart failure self-care is electronic weight scales.[11] However, this method presents only 23% sensitivity for early warning of Pulmonary

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[9] JM Vinson et al., *Early Readmission of Elderly Patients with Congestive Heart Failure,* J Am Geriatric Soc.,38: 1290–5, abstract ("25 first readmissions (38%) were judged possibly preventable, and 10 (15%) were judged probably preventable") (1990) abstract available at http://www.ncbi.nlm.nih.gov/pubmed/2254567.

[10] Indications for device therapy are expressed in the standard American College of Cardiology/American Heart Association (ACC/AHA) format which consists of multiple "Classes," where "Class I" is the highest. "Class I" refers to conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful and effective.

[11] *See, e.g.,* Clyde W. Yang et al, *2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines*, Circulation, 128:e240-e327 (2013) ("Patients need to understand how to monitor their symptoms and weight fluctuation ....") available at http://circ.ahajournals.org/content/128/16/e240.short?rss=1&ssource=mfr. *See also* William T. Abraham et al., *Intrathoracic Impedance vs Daily Weight Monitoring for Predicting Worsening Heart Failure Events: Results of the Fluid Accumulation Status Trial (FAST),* Mar-Apr;17(2):51-55, 54 (2011) ("Abraham Paper") ("Despite the poor performance of daily weight assessment, it

Edema,[12] and suffers from poor patient compliance. Other non-invasive technologies on the market have had very limited adoption, resulting from high pricing and poor performance. Some implantable medical sensors like those used with the CardioMEMS HF System have been developed to measure pulmonary artery ("PA") pressure. Increased PA pressures appear before weight and blood pressure changes, which are often used as ***indirect*** measures of worsening conditions that are a precursor to heart failure. While this type of sensor may be helpful in detecting the onset of heart failure indirectly, and can assist in chronic management of these patients, it does not measure lung fluid levels which are ***direct*** indicia of pulmonary congestion and patient deterioration. In addition, the invasiveness of these sensors renders them applicable to only a small subset of patients.

To address this significant unmet medical need, Kyma developed the uCor Device, a unique and advanced RF diagnostic device that non-invasively monitors lung fluid levels and trends. Data collected by a patient-worn uCor Device is transferred via a standard wireless interface (*i.e.,* Bluetooth) over the Internet and on to a data center where it can be analyzed by healthcare professionals to support timely patient counseling or clinical intervention. Based on its ease of use and reliability, the uCor Device has the potential to reduce hospitalizations, shorten hospital stays, reduce healthcare costs and improve quality of life for millions of CHF patients in the United States and around the world.

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has been viewed as the best available tool for monitoring outpatients with chronic HF, is strongly recommended by HF clinical practice guidelines, and is considered a major benchmark for assessing quality of care.") available at http://www.ncbi.nlm.nih.gov/pubmed/21449992.

[12] *See* Abraham Paper at 51.

The uCor 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 originating from the uCor propagate through the chest and lungs and reflect back from the heart. Since different types of tissue (*e.g.*, skin, muscle, fat, etc.) have different RF signal reflection properties that are highly affected by tissue hydration, an analysis of the reflected signal data permits healthcare professionals to determine fluid build-up in a CHF patient's lungs. The uCor Device is designed to take readings from a patient 6-8 times daily, each time for a short duration of up to sixty (60) seconds, typically while the patient is asleep and/or lying down.

Except for the frequency band of operation, the uCor Device will comply with all other technical and operational requirements applicable to UWB medical imaging devices. For example, the uCor Device will only be used under the direction of licensed healthcare professionals as required by Section 15.513(b); will cease operation in accordance with Section 15.513(c) through either a manual operator switch or via remote control;[13] and, as demonstrated in the test report attached herewith as Exhibit A, is capable of complying with radiated emission limits, average emission limits and peak level emissions applicable to UWB medical imaging devices as set forth in Section 15.513(d)-(f).

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[13] 47 C.F.R. Section 15.513(c) states: "A medical imaging system shall contain a manually operated switch that causes the transmitter to cease operations within 10 seconds of being released by the operator. In lieu of a switch located on the imaging system, it is permissible to operate an imaging system by remote control provided the imaging system ceases transmission within 10 seconds of the remote switch being released by the operator."

A prior version of the uCor Device ("Prior Device") was recently approved by the Commission[14] under the general emission limits in Section 15.209 governing unlicensed intentional radiators. However, because Section 15.209 devices are required to operate outside the Section 15.205 restricted bands, this earlier device exhibits a high degree of "ringing" -- an RF phenomenon that degrades obtainable depth resolution and thus, limits the accuracy of measuring lung fluid levels and trends which are important CHF parameters.

To address these problems, Kyma developed the "new" uCor Device to operate as a fast-stepping UWB radiator between 530 MHz and 2.105 GHz in approximately 25 MHz steps, with a cycle scan time of approximately 10 msec and a dwell time that is configurable between approximately 28 usec and 100 usec depending upon the specific parameter desired.[15] The uCor Device must operate in the lower frequencies because signals travel through the human body more efficiently in this part of the spectrum.[16] Specifically, the new design eliminates the "ringing" and unwanted oscillation that degrades depth resolution to provide more accurate readings on lung fluid levels and trends. It accomplishes this by operating as a UWB device in several of the Section 15.205 restricted bands.

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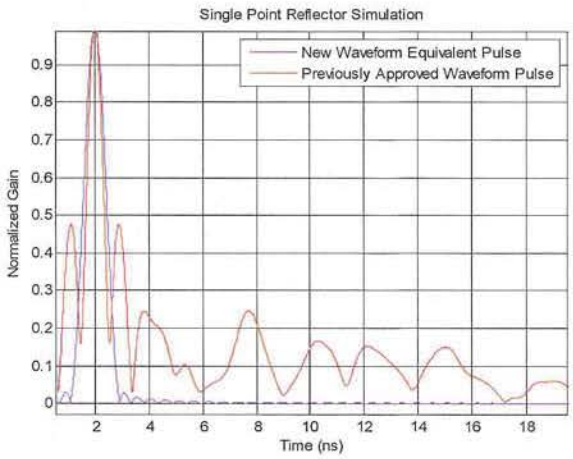
[14] *See* FCC ID: 2ABHFUCOR100.

[15] Kyma is currently assessing the benefits of variations of these parameters, including dwell time and step size, on the accuracy of data results. Accordingly, the waiver requested herein is intended for a dwell time that is configurable within the stated range.

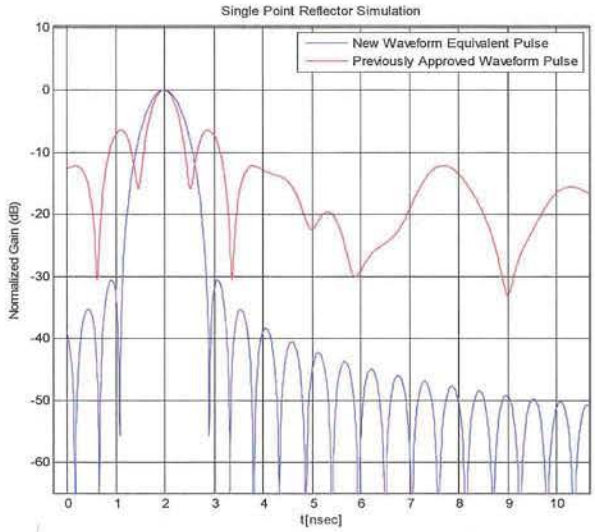
[16] *See, e.g.,* Sverre Brovall et al., *Optimal frequency range for medical radar measurements of human heartbeats using body-contact radar*, 35th Annual International Conference of the IEEE EMBS, Osaka, Japan 3 – 7 July, 2013 ("… the range of frequencies are limited by the EM properties of propagation in the human body" and "The results show that frequencies up to 2.5 GHz can be used for heartbeat measurements with body-contact radar").

Set forth below are the waveform representation graphs for the approved Prior Device and the new design of the uCor Device. Fluid content measurements are based on estimation of reflections at specific ranges attributed to specific tissue depths. The desired signals are extracted from clutter, where such clutter is primarily caused by reflections from adjacent tissue (*e.g.*, skin, fat and muscle layers) and exacerbated by the "skipping" over the Section 15.205 restricted bands. Specifically, skipping over the restricted bands creates a non-uniform spectrum that contains gaps which, when translated into a time domain signal, creates significant ringing effects and reduces accuracy. A high dynamic range of signal-to-clutter separation with low sidelobes is required to extract the desired signals.

The graphs show a few important things. For example, the first graph shows the effect of the ringing phenomenon on range resolution as evidenced by the "hills and valleys" pulse of the Prior Device (depicted in red) beginning from the 3 ns point on the first graph versus the almost flatline pulse of the uCor Device (depicted in blue). Range resolution is significantly enhanced with the uCor device which, because of its UWB characteristics, is not required to "notch" around the Section 15.205 restricted bands.



And in logarithmic scale (dB) units:



The second graph shows the varying pulse widths of the Prior Device and the uCor Device. When analyzing the graphs with a typical 10dB peak-to-sidelobe ratio, the width for the new waveform pulse of the uCor Device becomes ~1 nsec (*i.e.,* the width is the distance between approximately 1.5 and 2.5 nsec points on the -10dB x-axis on the chart immediately above), whereas the -10dB width for the approved Prior Device is ~2.5 nsec (*i.e.,* the width is the distance between approximately 0.8 and 3.2 nsec points on the -10dB x-axis on the chart immediately above). Insofar as a 2-fold reduction in pulse width improves depth resolution by the same amount, the new design translates into a 2-fold improvement in device sensitivity and accuracy. In clinical terms, due to the decompensation dynamics of CHF, this means that the early warning capability (*i.e.*, to alert patients of the onset of pulmonary congestion) will be increased from less than 1 day for the Prior Device to approximately 2-3 days for the new uCor Device. In terms of patient care, this means that CHF events can be detected much earlier than with existing technology and

treatment issues can be resolved by drug titration (and other steps) rather than through costly hospital admissions.

II. This Waiver Request Satisfies the Commission's General Standard for Granting Waivers and is Consistent with Recent UWB-Related Granted Waivers.

The Commission will waive its rules if it determines that the public interest will be served and the waiver will not undermine the policy of the rule to be waived.[17] The public interest arguments for a waiver of various UWB rules are set forth herein and present a compelling case for authorizing life-saving and life-sustaining technology like the uCor. In addition, the Commission's policy underlying its UWB rules will not be undermined because the uCor Device is a very fast stepping device that operates over 1.6 GHz of bandwidth and is very similar to the 3d-Radar device that was granted a UWB rule waiver.[18]

The Commission has shown a willingness to waive technical restrictions when a UWB device presents little threat of harmful interference and a waiver would further public interest goals. Indeed, many of the UWB waivers that have been granted involve the same types of issues for which Kyma seeks relief.

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[17] *WAIT Radio v. FCC,* 418 F 2d 1153 (D.C. Cir 1969). The Commission is authorized to grant a waiver under section 1.3 of the Commission rules if the petitioner demonstrates good cause. 47 C.F.R. § 1.3. Good cause may exist "where particular facts would make strict compliance inconsistent with the public interest." *Northeast Cellular Telephone Co. v. FCC,* 897 F.2d 1164, 1166 (D.C. Cir. 1990). There must be a strong public interest benefit in granting the waiver, and the waiver may not undermine the purposes of the rule. *Robert Bosch, GMBH Request for Waiver of Part 15 Rules Ultra-wideband Rules for a Wall-Imaging Device*, ET Docket No. 10-253, Order, 26 FCC Rcd 07572 (2011).

[18] *See 3d-Radar Waiver.*

For example, in 2008, the Commission granted a waiver to UltraVision Security Systems for a UWB surveillance system operating between 80 and 600 MHz and designed to warn of intruders on sites of strategic or commercial interest (even though the then current rules did not permit UWB surveillance systems below 1.99 GHz).[19] Similar to UltraVision, Kyma faces restrictive frequency band requirements that are unnecessarily limiting its ability to introduce new technologies that will benefit the public. UltraVision argued for a waiver to operate at a lower frequency than the UWB rules permitted on the basis that the UWB rules adopted in 2002 authorized the use of particular frequency bands based on the technologies known to the Commission at the time of the rulemaking proceeding.[20] Because UltraVision's technology did not exist at the time, the technology's operational needs did not factor into the Commission's decision regarding the lower frequency limit. Based on its innovative and unique technology which was designed to serve the nation's security needs in ways not otherwise possible under the rules, the Commission determined that the benefits of the surveillance system to protect property outweighed the potential risk of harmful interference, which can be managed through operational and technical restrictions.[21] Furthermore, the Commission determined that the waiver would serve the public interest by encouraging businesses (like UltraVision) to commit financial and other resources to provide important systems.[22]

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[19] *UltraVision Security Systems, Inc. Request for Interpretation and Waiver of Section 15.511(a) & (b) of the Commission's Rules for Ultra-Wideband Devices*, ET Docket No. 06-195, Order, 23 FCC Rcd 17632 (2008) ("*UltraVision Waiver*").

[20] *UltraVision Waiver* at ¶ 6.

[21] *Id.* at ¶ 13.

[22] *Id.* at ¶ 12.

The Commission has also shown a willingness to grant waiver requests involving other UWB rules. For example, the Commission granted a waiver in 2012 to Curtiss-Wright Controls, Inc. ("CWCI") regarding the specific minimum operational bandwidth of a UWB transmitter and the UWB measurement procedure outlined in Sections 15.503(d) and 15.521(d), respectively.[23] CWCI requested the waiver for its GPR system known as the 3d-Radar system, which was designed to increase efficiency in subsurface imaging. In granting the waiver, the Commission recognized that the device benefitted the public interest through lowering the costs of infrastructure repair and improving safety conditions for both infrastructure workers and the general public.[24]

In sum, the public interest will clearly be served if the Commission waives the specific rules and test procedures which are discussed below.

III. Consistent with Recent Precedent, Rule 15.503(d) Should be Waived to Permit a Fast, Stepped-Frequency Emitter Operating Over Approximately 1.6 GHz of Spectrum to Qualify as a UWB Device.

Section 15.503(d) of the Commission's rules defines a UWB 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."[25] Although the Commission's rules do not provide guidance as to what period of time constitutes an

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[23] *3d-Radar Waiver* at ¶ 24.

[24] *Id.* at ¶ 8.

[25] 47 C.F.R. Section 15.503(d).

instantaneous measurement interval, Commission staff previously considered the phrase "at any point in time" to be synonymous with "instantaneous," and that a single step in a stepped-frequency emitter would appear to be the instantaneous bandwidth for the device. Under this interpretation, the uCor Device would not satisfy the definitional requirement since each 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. Thus, Kyma seeks a waiver of Section 15.503(d).

An almost identical issue arose with the 3d-Radar GPR system which is also a fast, stepped-frequency emitter. In its request for a waiver of Section 15.503(d) for its device, CWCI identified the ambiguities in the rules as applied to continuous wave emitters and varying interpretations by FCC Lab staff as to how the definitional requirements are satisfied for such devices.[26] Section 15.503(d) was waived for the 3d-Radar system that operated over 2.8 GHz in 2 MHz steps or greater, with a scan time of 3 msec, dwell time of 2 usec and a duty cycle of 0.07%.[27]

The key factors which the Commission relied upon in granting the waiver of Section 15.503(d) for the 3d-Radar GPR system included the following: (i) the proposed device was functionally equivalent to UWB GPR devices permitted under the Commission's rules; (ii) risk of interference from the proposed device will be no greater than UWB devices that fall squarely within the rules (*e.g.*, operation of the devices is limited to the same eligible users permitted for UWB devices

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[26] *See Curtiss-Wright Controls Inc. Request for Waiver of Part 15 of the Commission's Rules Applicable to Ultra-Wideband Devices,"* filed June 10, 2010, ET Docket No. 10-167 at pp. 3-6 ("*CWCI Waiver Request*").

[27] *See 3d-Radar Waiver* at ¶ 14.

(thereby limiting interference potential)); (iii) new devices will operate under the same emission limits (and other technical requirements), marketing and eligibility requirements applicable to similar UWB devices that fall within the definition of UWB; and (iv) there was a legitimate public interest justification (*i.e.*, new tool to aid public safety).[28]

Similarly, the uCor Device will be functionally equivalent to UWB devices permitted under the Commission's rules (though, as discussed later, Kyma is unaware of any UWB medical imaging devices actually having been approved by the Commission). For example, the uCor Device operates only when in contact with the human body for the purpose of obtaining images/diagnostic information and its energy is intentionally directed into the human body which absorbs most of the energy. The device has a low duty cycle – it would be used by a patient only a few times a day, each time for up to sixty (60) seconds. In addition, the level of potential interference from the uCor Device will be no different than what would be expected for an UWB medical imaging system. Since the device will comply with emission, marketing and other requirements applicable

[28] Specifically, the Commission stated: "We find that the 3d-Radar device is functionally equivalent to UWB GPR devices and that the risk of interference from the 3d-Radar device will be no greater than from UWB GPR devices; thus, a waiver will not undermine the intent of our rule. At the outset, we emphasize that the 3d-Radar device is a GPR that will operate like UWB GPR devices -- *i.e.*, it operates when in contact with or within one meter of the ground for the purpose of detecting or obtaining images of buried objects, and its energy is intentionally directed down into the ground, which absorbs most of its energy. In addition to restricting emissions and requiring coordination, the Commission's UWB GPR rules also limit the operation of these devices to certain eligible parties to ensure that proliferation of the devices remains low, thereby further curtailing their interference potential. Because we are not waiving the requirements in Section 15.509 of our rules, the 3d-Radar will operate under the same emission limits, marketing and eligibility requirements and will provide the same types of services as UWB GPR devices. .... We also find that there is a legitimate public interest justification for this waiver. The 3d-Radar device is a new tool for evaluating and improving road and railroad infrastructure and will aid public safety." *3d-Radar Waiver* at ¶¶ 14 and 18. Footnotes within quoted text intentionally omitted.

to similar UWB devices (*e.g.*, used under the direction of licensed healthcare professional) and will be used primarily indoors, the potential for harmful interference will be further reduced. Finally, the impact on CHF patients in terms of improved survival rates, reduced hospitalization, improvements in quality of life and reduced healthcare costs serve the public interest.

For the reasons set forth above, Kyma respectfully requests that the Commission waive Section 15.503(d) to the extent necessary to qualify the uCor Device as a UWB device.

IV. Consistent with Recent Precedent, the UWB Test Procedures Should be Waived to Allow Average Measurements Above 960 MHz to be Made With the Stepping Function Active.

The test procedures for UWB devices are set forth in section 15.521(d) of the Commission's rules. For emissions above 960 MHz, the rule requires measurements to be made with an RMS average detector over a 1 MHz resolution bandwidth. The rule also provides 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."[29]

By its terms, this measurement procedure applies only to pulsed UWB devices. However, Commission staff has in the past applied it to other types of emitters, including stepped frequency

[29] 47 C.F.R. Section 15.521(d). The Commission's rules also state that "alternate measurement procedures may be considered by the Commission." *Id.* To the extent that the Commission decides not to waive this test procedure requirement for the uCor Device notwithstanding recent precedent cited herein, Kyma alternatively asks the Commission to allow Kyma to move forward with its proposed test procedures with the stepping function active pursuant to this provision.

systems.[30] When the Commission adopted the UWB rules, it recognized that it would be necessary to revisit its conservative rules to adopt more flexible standard.[31] In fact, the Commission has revisited its UWB rules governing measurement procedures and permitted measurements on a stepped frequency system to be performed with the stepping function active.

For example, in the *MBOA-SIG Waiver*, the Commission permitted UWB transmitters operating above 960 MHz that use stepped frequency modulation to be measured using an average detector with the transmitter operating in its normal mode (*i.e.*, with the stepping function active).[32] With respect to the *MBOA-SIG Waiver*, the Commission acknowledged that having the stepping function active allows measurements to account for the time averaging during which the UWB emitter is not transmitting.

Most recently, CWCI sought a similar waiver of Section 15.521(d) and pointed to the *MBOA-SIG Waiver*, among other things, to support its request.[33] CWCI argued that if emissions from its 3d-

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[30] This more expansive interpretation appears to originate from language in the *2002 UWB First Report and Order* where the Commission said that "measurements on a stepped frequency or frequency hopping modulated system are performed with the stepping frequency or frequency hop stopped." *2002 UWB First Report and Order* at ¶ 32.

[31] *See 2002 UWB First Report and Order* at ¶ 1.

[32] *See, e.g.*, *MBOA-SIG Waiver* (waiver granted for UWB transmitters (which met the UWB bandwidth requirements) operating in the 3.1 – 5.03 GHz and 5.65 -10.6 GHz bands that employed frequency hopping or stepped frequency modulation techniques, or that gate the transmitted signal to be measured with the transmitter operating in its normal transmission mode).

[33] See *CWCI Waiver Request* at pp 7 – 10. Kyma assumes that the justifications for permitting a waiver of the Section 15.521(d) to allow the stepping function to be active are well settled and, therefore, Kyma will not repeat in this filing all of the arguments on this point that are presented in the *CWCI Waiver Request*.

Radar device are measured with the stepping function stopped under the rule, peak emissions would need to be reduced significantly to achieve compliance, and this would force the system to operate at reduced performance levels. Kyma faces the same issue with the uCor Device if its device is measured with the stepping function stopped.

In the *3d-Radar Waiver*, the Commission waived the Section 15.521(d) requirement and concluded that there is "good cause for waiving the rule in this case and that such action would serve the public interest."[34] Specifically, the Commission stated that its:

> finding in the *MBOA-SIG Waiver* that emission measurements could be made for a stepped frequency modulated transmitter operating in its normal mode is equally valid for the 3d-Radar device. The Commission, in conjunction with the NTIA, determined that allowing stepped frequency devices to be measured with the stepping function on will not increase the interference potential of the device above that of impulse UWB devices if all other emission limits and technical requirements are met. Similarly, we conclude here that a waiver of the measurement procedure in Section 15.521(d) will not increase the potential for harmful interference to authorized services.[35]

The Commission referenced its analysis in the *MBOA-SIG Waiver* and concluded in the *3d-Radar Waiver* "that any requirement to stop the frequency hopping, band sequencing, or system gating serves only to add another unnecessary level of conservatism to already stringent UWB standards."[36]

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[34] *3d-Radar Waiver* at ¶ 21. Although the Commission did not believe that the 3d-Radar device could rely on the *MBOA-SIG Waiver* decision without a "new" waiver (since the 3d-Radar device did not meet the UWB bandwidth requirements of 15.503(d) like the device covered by the *MBOA-SIG Waiver*), the Commission ultimately decided that a new waiver of this rules was merited even for a device that did not satisfy the definitional requirements of UWB device. *Id.* at ¶ 22.

[35] *Id.* at ¶ 22.

[36] *Id.* at ¶ 21.

The uCor Device merits a waiver for the same reasons as the 3d-Radar device. A waiver of the measurement procedure for the uCor Device will not increase the potential for harmful interference to existing spectrum users given its low duty cycle, indoor use and low power which will be largely absorbed by the patient's body.

For the above reasons, Kyma seeks a waiver of this rule to permit it to measure emissions from its system under normal operating conditions – *i.e.,* with the frequency stepping function active.

V. Rule 15.513(a) Should be Waived to Permit a Medical Imaging System to Operate Below 3.1 GHz.

Section 15.513(a) of the Commission's rules limits the use of all Part 15 UWB medical imaging devices to spectrum between 3.1 GHz - 10.6 GHz. This operating range was adopted by a cautious Commission in its *2002 UWB First Report and Order* (which amended the Part 15 Rules to permit the marketing and operation of new products incorporating UWB technology) as a way to strike a balance between protecting existing spectrum users from potential interference and promoting new UWB technologies.[37]

As discussed more fully below, the frequency band limitations imposed on UWB imaging systems (including medical imaging) were adopted in response to the uncorroborated and theoretical interference concerns of certain existing spectrum users. These incumbent operators simply did not want any more spectrum users in their "spectral backyard." Unfortunately, there was no one

[37] *See, e.g., 2002 UWB First Report and Order* at ¶¶ 17 and 18.

to challenge these concerns on behalf of the UWB medical imaging device industry since no such "industry" existed in 2002. To its credit, the Commission recognized this and sprinkled the *2002 UWB First Report and Order* with acknowledgments that its new UWB imaging system frequency limits "reflect an abundance of caution" to protect incumbent users,[38] and that the Commission was open to explore more flexible technical standards in the future as the agency obtained more experience with new UWB technologies.[39]

Through this waiver request, Kyma respectfully asks the Commission to follow-through with the flexibility it contemplated when it adopted its UWB rules, and to permit the uCor Device to operate below 3.1 GHz. As previously discussed, the spectrum between 530 MHz and 2.105 GHz is ideally suited, if not a necessity, for transmission into the human body. In addition, as noted above, the use of the Section 15.205 restricted bands (which can be used by UWB devices) is necessary to eliminate the "ringing" that degrades depth resolution and accuracy of lung fluid level readings.

A. UWB Medical Imaging Technology has not Developed Since the 2002 UWB Rules were Adopted.

The Commission has long recognized that UWB technology holds significant potential for the development of new devices and applications while increasing the use of scarce spectrum resources by sharing frequencies with other services.[40] As evidenced by its adoption of rules expressly covering UWB medical imagining devices, the Commission expected these types of

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[38] *Id.* at ¶ 56.

[39] *Id.* at ¶ 1.

[40] *See Id.* at ¶ 12.