Federal Communications Commission
Washington, D.C. 20554

November 30, 2011

DA 11-1951

Ms. Cheryl A. Tritt
Mr. Phuong Pham
Counsel for Second Sight Medical Products, Inc.
2300 N Street, NW, Suite 700
Washington, D.C. 20037

Re: ET Docket No. 11-123

Dear Ms. Tritt and Mr. Pham:

The Office of Engineering and Technology (OET) is granting the request of Second Sight Medical Products, Inc. (Second Sight) for waiver of Section 15.209(a) of the Commission's rules to allow it to obtain FCC certification for and market its Argus II™ Retinal Prosthesis System (Argus II). In your letter filed May 27, 2011, you state the Argus II is a medical implant system designed to treat profoundly blind people suffering from advanced retinal degenerative diseases such as Retinitis Pigmentosa.[1] You state that the system consists of a neurostimulator surgically implanted on the eye, a pair of eyeglasses housing a miniature video camera, and an external video processing unit connected to the eyeglasses via cable.[2] The video camera captures images that are converted into instructional signals by the video processing unit and are sent back to the eyeglasses to be wirelessly transmitted to the implant. You also state that the eyeglasses inductively transmit both data and power to the implant on the carrier frequency 3.156 MHz.[3]

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[1] *See* Second Sight Medical Products, Inc. Request for Waiver of Section 15.209(a) of the Commission's Rules to Permit the Operation of Medical Implantable Devices for the Treatment of Advanced Retinal Degenerative Diseases (Request) dated May 27, 2011, from Cheryl Tritt and Phuong Pham, Wilkinson Barker Knauer, LLP. The request for waiver was placed on Public Notice July 20, 2011. *See Office of Engineering and Technology Declares the Second Sight Medical Products, Inc. Request for Waiver of Rule Section 15.209(A) to be a "Permit-but –Disclose" proceeding for Ex Parte Purposes and Requests Comment*, ET Docket No. 11-123, DA 11-1213. Second Sight filed comments in support of its waiver request; no other comments were received.

[2] *See* Request at 3-5.

[3] *See* Request at 6. The 3.156 MHz signal is 13 kHz wide and covers both the 3.025-3.155 MHz Aeronautical Mobile and the 3.155-3.230 MHz Maritime bands. The 3.155-3.230 MHz band is allocated to fixed and mobile, except aeronautical mobile route services, on a primary basis for Federal and non-Federal users and is authorized for Private Land Mobile Radio (PLMR) services. The 3.025-3.155 MHz band is allocated to aeronautical mobile off-route services on a primary basis for Federal and non-Federal users. In addition, under United States Footnote 340 (US340), the 2-30 MHz band is available on a non-interference basis to Federal and non-Federal maritime and aeronautical stations for the purpose of measuring the quality of reception on radio channels. *See* 47 C.F.R. § 2.106, International Footnotes 5.116 and 5.117, US340, and § 18.301.

You state that the eyeglasses' transmission of power to the implanted device complies with the Commission's Part 18 Rules for ISM equipment.[4] You further state that the transmission of data signals from the implant to the eyeglasses on the frequency 481.5 kHz complies with applicable emission limits as specified in Part 15 of the Commission's rules.[5] However, the transmission of power signals from the eyeglasses to the implant also serves as the carrier for the data signals, and these emissions exceed the limit for unlicensed intentional radiators contained in Section 15.209 of the Commission's Rules.[6] Specifically, Section 15.209 limits the emissions of unlicensed intentional radiators operating within the 1.705-30 MHz band to a field strength of 30 microvolts per meter (μV/m) at a measurement distance of 30 meters.[7] The Argus II operates with power and data emissions of approximately 22 to 93 μV/m at 30 meters. You request that we waive Section 15.209(a) to allow current and future generations of the Argus II to operate with emissions not to exceed 119 μV/m at 30 meters.[8] You also indicate that allowing emissions at this higher level would facilitate global deployment of the devices.[9]

In support of your request, you state that requiring Second Sight to redesign the Argus II to comply with the emission limit allowed under Section 15.209(a) would render the equipment effectively useless and incapable of performing critical functions. You further state that the center frequency of 3.156 MHz is ideal for both ensuring adequate power to the implant and avoiding excessive power absorption in a user's body, which would occur at higher frequencies. You claim that Second Sight would have to add larger electronics and an additional coil antenna to redesign the Argus II to perform power and data transmission on different frequencies. This would reduce operating efficiencies and increase the cost, size, and weight of the device.[10]

In further support of your request, you state the Argus II's communications sidebands that are produced by modulating their 3.156 MHz carrier frequency comply with the Section 15.209(a) limits.[11] Moreover, you submit that all spurious emissions also comply with the Section 15.209(a) limits. In addition, you argue that operation of the Argus II is highly

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[4] Under part 18 of the Commission's Rules, equipment operating on any non-ISM Frequency is limited to a field strength of 15 μV/m at a distance of 300 meters. *See* 47 C.F.R § 18.305.

[5] Under Part 15 of the Commission's Rules, unlicensed intentional radiators may also be operated in the 3.156 MHz band. *See* 47 C.F.R. § 15.209.

[6] *See* Request at 7-8.

[7] *See* 47 C.F.R. § 15.209 (a).

[8] *See* Request at 1, 2, 7-8, 13-14.

[9] *See* Request at 14.

[10] *See* Request at 14-15, See also Vinit Singh, et al., *Specific Absorption Rate and Current Densities in the Human Eye and Head Induced by the Telemetry Link of an Epiretinal Prosthesis*, 57 IEEE Transactions on Antennas and Propagation 3110, 3110-3118 (Oct. 2009).

[11] *See* Request at 7.

unlikely to cause harmful interference to licensed Maritime or PLMR systems in the 3.025-3.230 MHz (3.156 MHz) band because these systems operate at, or well above, 100 watts.[12] You submit that interference to licensed systems is further reduced because the system directs low-power signals towards the neurotransmitter implant in the patient's body by induction and that the maximum operating range is limited to 20 millimeters. You also contend that under Section 15.223(a) of the Commission's rules, similar devices are allowed to operate at maximum emission levels of 100 μV/m at a distance of 30 meters.[13] You argue that permitting the operation of Part 15 devices at these emission levels suggests that licensed systems are unaffected by low-power devices and the Argus II would not adversely affect licensed systems when operated under the same emission limits.[14]

In your request, you also submit that granting Second Sight a waiver for the Argus II will be in the public interest because it would offer substantial benefits for blind persons with retinal degenerative diseases. The Argus II is the only approved treatment for patients suffering from Retinitis Pigmentosa, as the retina cannot be replaced by artificial lenses, corrected with surgery, or cured with drugs.[15] Moreover, you state that providing a waiver for the Argus II could restore a patient's sense of vision and allow him or her to regain a measure of mobility and self-sufficiency, which, in turn, could reduce the cost of healthcare and in-home care for patients, while substantially improving their quality of life.[16] Finally, you argue that granting this waiver would be consistent with the previously established *EnteroMedics*[17] precedent wherein the Commission waived Section 15.209 to allow an implanted device used to treat

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[12] *See* Request at 12-13.

[13] *See* 47 C.F.R § 15.223(a). This section of the rules provides that "[t]he field strength of any emission within the band of 1.705-10.0 MHz shall not exceed 100 μV/m at a distance of 30 meters. However, if the bandwidth of the emission is less than 10% of the center frequency, the field strength shall not exceed 15 μV/m or (the bandwidth of the device in kHz) divided by (the center frequency of the device in MHz) microvolts/meter at a distance of 30 meters, whichever is the higher level. For the purposes of this section, bandwidth is determined at the points 6 dB down from the modulated carrier. The emissions in this paragraph are based on measurement instrumentation employing an average detector. The provisions in §15.35(b) for limiting peak emissions apply." The Argus II would not be allowed to operate at the 100 μV/m emission limit of this section because the 13 kHz bandwidth of the device is less than 10% of the 3.156 MHz center frequency. We note that the emission limits presented in § 15.209 (a) and §15.223(a) require field strength measurements to be taken with equipment employing two different detector types. § 15.209 requires measurement instrumentation employing a quasi-peak detector, while § 15.223 requires measurement instrumentation employing an average detector. In general, the field strength limits presented in each of these sections are not directly comparable. However in this case, the two different measurement detectors should yield similar results given the relatively narrow bandwidth of the Argus II.

[14] *See* Request at 13-14.

[15] *See* Request at 9-10. *See also* The Foundation Fighting Blindness, Retinal Degenerative Diseases, http://www.ffb.ca/eye_conditions/RD_diseases.html , http://www.ffb.ca///eye_conditions.html (accessed Sept 1, 2011).

[16] *See* Request at 12.

[17] *See* Letter from Julius P. Knapp, Chief, Office of Engineering and Technology, FCC, to Mitchell Lazarus, Counsel for EnteroMedics Inc., 24 FCC Rcd 13795, 13796 (OET 2009) (EnteroMedics).

gastro-intestinal disorders to operate at field strengths up to 200.2 μV/m at 30 meters for transmission of both power and communications signals at a frequency of 6.78 MHz.[18]

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.[19] Good cause, in turn, may be found and a waiver granted "where particular facts would make strict compliance inconsistent with the public interest."[20] 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.[21]

Based on the submissions presented in this request, we find that a waiver permitting the Argus II unlicensed device to operate with a center frequency of 3.156 MHz and carrier bandwidth of 13 kHz in the 3.025-3.230 MHz band with emissions higher than those permitted by Section 15.209(a) of the Commission's Rules, up to 119 μV/m at 30 meters is warranted.[22] We believe that the purpose underlying the emissions limit in the Rules would not be undermined by applying the requested limit to current and future generations of the Argus II because it is unlikely that licensees in the 3.025-3.230 MHz band will experience harmful interference from the operation of these devices at the power levels and operating conditions indicated. We also note that, while the Argus II does not operate in a designated ISM band, the power transfer function of the Argus II complies with the requirements for medical implant devices contained in Part 18 of the Commission's Rules. Furthermore, the intended use and the short distance between the implanted neurostimulator and the external eyeglasses antenna will keep the power requirements necessary for successful communications low which, in turn, will minimize the potential for interference.

Moreover, we recognize that the neurostimulator implant of this system is designed to operate optimally and less intrusively by performing the communication and power transfer functions at a single frequency, and we conclude that no useful purpose would be served by requiring that these functions be performed on separate frequencies for this type of device. In addition, we note that there is no more interference potential from allowing the Argus II's communication signal emissions to exceed the limit specified in Section 15.209(a) than if the

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[18] *See* Request at 2, 15-16 (citing *EnteroMedics* at FCC Rcd 13798).

[19] 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).

[20] *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.

[21] *See, e.g.*, *WAIT Radio*, 418 F.2d at 1157 (stating that even though the overall objectives of a general rule have been adjudged to be in the public interest, it is possible that application of the rule to a specific case may not serve the public interest if an applicant's proposal does not undermine the public interest policy served by the rule); *Northeast Cellular*, 897 F.2d at 1166 (stating that in granting a waiver, an agency must explain why deviation from the general rule better serves the public interest than would strict adherence to the rule).

[22] We are permitting the Argus II to operate with emissions up to 119 μV/m at 30 meters based on measurement instrumentation employing a quasi-peak detector.

device used different electronics to generate separate compliant power and communication signals that were simultaneously transmitted at 3.156 MHz.

We also conclude that grant of a waiver to Second Sight will serve the public interest by partially restoring vision to blind persons affected by retinal degenerative diseases. In turn, this could increase patient mobility and independence, which could result in lower health care costs and enhance the quality of life for these individuals. We further conclude that allowing the Argus II to operate at the 119 μV/m emission levels will decrease development and manufacturing costs and facilitate global deployment of the device.

Thus, given the device's intended use and the limited interference potential, we conclude that this request is consistent with the previously established *EnteroMedics* precedent and that a waiver of the emission limits of Section 15.209(a) is warranted. This waiver applies only to current and future generations of this specific vision restoration system, however, and is not to be considered to apply generally to other devices. In accordance with Section 15.5(b) of the Commissions Rules, operation of Argus II is subject to the conditions that no harmful interference is caused and that interference must be accepted by other users of the spectrum.[23]

Accordingly, pursuant to the delegated authority in Sections 0.31, 0.241, and 1.3 of the Commission's Rules, 47 C.F.R. §§ 0.31, 0.241, 1.3, we waive the requirements of Section 15.209(a) of our Rules to allow Second Sight Medical Products, Inc. to obtain FCC certification for and market its Argus™ II Retinal Prosthesis System that operates at a transmit frequency of 3.156 MHz with carrier bandwidth of 13 kHz, with external emissions not to exceed 119 μV/m at measurement distance of 30 meters.

Sincerely,

Julius P. Knapp
Chief
Office of Engineering and Technology

[23] *See* 47 C.F.R. § 15.5(b). Operation of an intentional, unintentional, or incidental radiator is subject to the conditions that no harmful interference is caused and that interference must be accepted that may be caused by the operation of an authorized radio station, by another intentional or unintentional radiator, by industrial, scientific and medical (ISM) equipment, or by an incidental radiator. This information is required to be displayed under the labeling requirements in 47 C.F.R. § 15.19.