Joerg Kusig

Von: Joerg Kusig

Gesendet: Mittwoch, 23. Mai 2012 10:19

An: Tim.Harrington@fcc.gov

Cc: Hussein Halawi; gunnar.boersch@biotronik.com; Sandra Henke; Andrea Lehmann

Betreff: FCC Equipment Authorization System - Correspondence Reference Number: 41690 - 731 Confirmation Number: EA447863

Anlagen: Q1a - QRILUMAXT50 Ref 41690.jpg; Q1b - QRILUMAXT50 Ref 41690.jpg; Q2+3 - QRILUMAXT50 Ref 41690.pdf; Q8 - QRILUMAXT50 Ref 41690.jpg

Dear Mr Harrington,

Please find the responses to your questions below in „blue" and in the attachment.
The responses are arranged on behalf of the manufacturer and the lab which performed the measurement. The statements, pictures and drawings were made available by this parties.

Best Regards!

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To: Gunnar Boersch,
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From: Tim Harrington
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FCC Equipment Authorization Branch
Applicant: BIOTRONIK SE & Co. KG
FCC ID: QRILUMAXT50
Correspondence Reference Number: 41690
731 Confirmation Number: EA447863
Date of Original E-Mail: 4/26/2012
Subject: FCC Equipment Authorization System

1) a) Unless it is already shown in the internal photos, please revise/amend to also show the MedRadio antenna,
with the associated connections and chassis assembly components.
1) b) For internal photos, please explain and/or show what/where is the telemetry antenna coil

Response to #1a/b
The device has two antennas.
Antenna size and location of the 402 to 405 MHz Med Radio are shown as a red line in the attached picture Q1a - QRILUMAXT50 Ref 41690.jpg.
The second antenna is a low frequency 32 kHz telemetry antenna coil. Size and location are shown in the attached picture Q1b - QRILUMAXT50 Ref 41690.jpg.
The 32 kHz telemetry system is designed for "very" near field communication. And is far below the 40dB under 15.209 limit line requirement. See also question #5 response.

2) a) Op. desc. mentions "TELEC T241"; as appropriate please revise to explain what that is, how is it relevant for FCC rule requirements, etc.; or revise to be only in terms of specific FCC requirements.
2) b) Op. desc. mentions "MICS" - fyi that term is obsolete in FCC rules. At minimum for ALL future filings, please ensure that all relevant exhibits are in terms of the most recent 47 CFR in effect at the time of application submission; i.e. use "Med Radio" not "MICS", see also part 95 section numbering changes per 77 FR 4252-4271 (FCC-11-176), etc.

Response to #2a/b
Please find a revised version of the operational description in the attachment Q2+3 - QRILUMAXT50 Ref 41690.pdf and delete the former version of the operational description.

3) Various exhibits seem to indicate this filing is intended to cover several different versions of implant transmitters. Various designations used herein include: "740 HF-T", "640 DR-T", "TACH50", "600/700",
Unless in the filing already, please provide list and photos or engineering drawings for all versions intended under this FCC ID, and with brief description for what are differences for each, i.e. external dimensions, header configurations, etc.

Response to #3
Please find a revised version of the operational description in the attachment Q2+3 - QRILUMAXT50 Ref 41690.pdf. It explains the model differences in detail.

4) Please identify specific and/or typical FCC ID(s) of other device(s) subject to FCC equipment authorization intended to operate together in a session with this implant transmitter as part of an inductive telemetry system.

Response to #4
The Lumax implant works together with the programming and diagnostic system Renamic: FCC ID: QRIRENAMIC

5) Page 5 of the 15.209 test report appears to indicate this implant device has a telemetry transmit fundamental signal at 32 kHz. Pages 12-13 indicate a spurious emission measurement result at 48 kHz.
Note that the 15.209(a) "emissions from an intentional radiator" provision includes also the fundamental signal. Unless in the filing already, as appropriate compliance to 15.209 limits also needs to be demonstrated for the 32 kHz emission [also 15.209(c), as appropriate]. Please explain and/or revise accordingly.
In case the fundamental signal field strength is not 40 dB below the limit, then 15.201 requires Certification also for the intentional radiator portion; i.e. an additional form-731 (composite) application must be submitted, containing complete 2.1033(b) information.

Response #5
After detailed consultation with the test lab we can confirm that because of the extrem near field transmission character of the inductive system the 32 kHz carrier and its harmonics, even in a three meter measurement distance, do no show up above the noise floor. The 32 kHz transmitter was active during the measurement and no notch filter was used to supress the 32 kHz carrier. Accordingly, the 32 kHz transmitter is more than 80 dB below the 15.209 limit line. The 48 kHz peak cannot be directly traced back to the inductive telemetry system and is generated by a different source.

6) Part 95 test report mentions 95.628 sections. This application was submitted March 19, 2012. FYI as of Feb. 27, 2012, 95.628 was renumbered to be 95.627. A revised test report is not required for this application, but can be submitted at applicant's discretion. Please ensure at minimum all future filings from this grantee are terms of the 47 CFR versions in effect at the time of submission.

Response to #6
Thanks for the comment. All future filings will follow the new numbering system.

7) For fyi only, filing change not required, note that FCC has does have KDB pub. 617965, i.e. 95.639(f) testing can use other the Hartsgrove et al tissue parameters (Table 2 therein, 400 MHz, eps = 62.5, sig = 0.9 S/m) or OET Bull. 65 Suppl. C parameters (http://transition.fcc.gov/oet/rfsafety/dielectric.html, 403.5 MHz, eps = 57.9, sig = 0.82 S/m). FYI it might be possible that in the future FCC will require use of only OET B 65 Suppl. C parameters.

Response to #8
Thanks for the comment, we will discuss the option with our lab.

8) Part 95 test report indicates that measurements were done with direct connection at the RF output. Please submit test setup photo for this condition, and due to that confid. was requested for internal photos (generally would not qualify for test setup photos), the portions of the circuit board etc other than the RF connector and general outline of the device can be "whited-out" in the photo.
The items indicated above must be submitted before processing can continue on the above referenced application. Failure to provide the requested information within 60 days of the original e-mail date may result in application dismissal and forfeiture of the filing fee pursuant to Section 1.1108

Response to #8:
Because of the highly integrated and dense design and partly flexible board the conducted measurement can only be performed with the help of an evaluation board. The board provides the power supply, signalling and gives mechanically stability. The tested device is almost completely encased by the evaluation board and not visible.
Please refer to the attached picture Q8 - QRILUMAXT50 Ref 41690.pdf which shows the test set up for conducted measurement.

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Any questions about the content of this correspondence should be directed to the e-mail address listed below the name of the sender