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Response to FCC Equipment Authorization in Blue below the findings:

Applicant:	BIOTRONIK SE & Co. KG
FCC ID:	QRIPRIMUSNXT
731 Confirmation Number:	EA310957

Adminstrative Review by Evelyn Cherry:

Correspondence Reference Number:	44433
Date of Original E-Mail:	9/16/2013

FCC:
An administrative review of this application filing shows that the required fee has been paid and verified. Please sign and date the exhibit under operational description. The confidentiality request must reference both Sections of the FCC Rules 0.457 and 0.459 as the authority for granting confidentiality. The exhibit uploaded beginning with the #24 requires a signature, date if not dated, and the request must be provided on official company's letter head.

Response by applicant:
1. A revised version of the confidentiality letter signed by the applicant is attached. The document number is 05_PRIMUSXT ConReq-U rev1. Please be informed that the applicant asks for permanent confidentiality of the internal pictures and has this document type added to the list. The implant is completely sealed by welding and cannot be opened without destroying. Furthermore we attached versions of the 95I test report without pictures of the device for the public database with document numbers: “14a_PRIMUSNXT TestRep 95I without product photo”s and “14b_PRIMUSNXT TestRep 15.209 without product photos”
2. A signed version of the short term confidential request: 24_PRIMUSNXT ShortConReq rev1. is attached. It is dated and provided on company’ letter head

Technical Review by Travis Thul:

Correspondence Reference Number:	44440
Date of Original E-Mail:	9/18/2013

1. FCC: The Equipment Code listed under Equipment Specifications is currently set to TNB – Licensed Non-Broadcast Station Transmitter. This designation should be set to TNT – Non-Broadcast Transmitter Worn on Body. This change has been made to your application and requires no action on the part of the submitter.

   Response by applicant:
   Thanks for the correction, we are going to specify all future application for med radio implants to TNT.

2. FCC: Per 47 CFR 95.1215, the specific verbiage found in paragraph (a) of that section must be included verbatim with each device. This is acknowledged in the exhibit titled “06_07 Labeling_PRIMUSNXT”, but is not reflected in the exhibit titled “15_PRIMUSNXT UserMan” (the User’s Manual). Please update documents in accordance with 47 CFR 95.1215.

   Response by applicant:
   A revised version of the user manual is attached; document name: 15_PRIMUSNXT UserMan rev1. It shows the exact wording of the text statement per 47 CFR 95.1215 on page 19.

3. FCC: The exhibit titled “11_PRIMUSNXT OpDes” indicates conformity with 47 CFR Part 24. This is erroneousas Part 24 is specific to Personal Communications Services. Please update documents accordingly

   Response by applicant:
   A revised version of the operational description is attached, document number: 11_PRIMUSNXT OpDes rev1. The correct rule part is 95I

4. FCC: The Emission Designator within the submitted Equipment Specifications has been listed as 188KF1D (equating to a bandwidth of 188 kHz). However, the type of emission within the exhibit titled “11_PRIMUSNXT OpDes”, is given as 230KF1D (equating to a bandwidth of 230 kHz). Please clarify this deviation and update package accordingly

   Response by applicant:
   A revised version of the operational description is attached, document number: 11_PRIMUSNXT OpDes rev1. The bandwidth is changed to the exact measured value of 188 kHz, see also test report.

5. FCC: The exhibit titled “12_RPIMUSNXT BlkDia” shows a 27nH inductor connected outside of the main device housing. It is unclear what role this inductor plays during communications between the primary device and the programming unit (referred to as the “Programmer” within the User’s Manual). Please clarify. If the inductor functions as an antenna, please update documentation to reflect as much, under what circumstances this is the case, and describe the communications link

   Response by applicant:
   The 27 nH coil is the radiation element of the 64kHz coil telemetry feature of the device. It is a near field communication system between a magnetic programmer head and the implant and hardly detectable even in short distance. Test report 14b_PRIMUSNXT TestRep 15.209 shows that the transmit power at 64 kHz is more than 40dB below the spurious emission limit and the telemetry function is not subject of certification.

6. FCC: The power output value within the submitted Equipment Specifications indicates a maximum output power of 0.8uW (-30.97dBm). This value deviates from the worst-case maximum output power of 93.154uW shown within the exhibit “18a_PRIMUSNXT RFExp”. The output power value has been updated to reflect the value found within the exhibit and the change has been noted in the package.

   Response by applicant:
   The maximum output power of 0.8uW in the rf report and Equipment Specification is radiated e.i.r.p. according to the requirements of 95.639(f). The RFExp calculation is based on the maximum conducted output power (93.154uW) to consider the worst case near field effects. The “bad” antenna gain of more than factor -100 (-21.6 dBi) is due to the very limited room for the antenna dimension at a relatively lower frequency of about 400 MHz.

7. FCC: The exhibit titled “14b_PRIMUSNXT TestRep 15.209” shows testing using a center frequency of 64 kHz. However, all supporting documentation omits further description or elaboration of this transmitting mode. It should be noted that, per 47 CFR 15.201(a), devices operating below 490 kHz in which all emissions are at least 40 dB below the limits in 15.209 shall be verified per 47 CFR Part 2, subpart J. If this is the case, the package will need to be updated accordingly

   Response by applicant:
   The report 14b_PRIMUSNXT TestRep 15.209 was submitted to demonstrate that the coil telemetry (64kHz) function transmitted by the 27mH coil of the device is far below the 40 dB below 15.209 limit and not subject of certification. A short description of its function can be found in the user manual page 3 “programmer”.

8. FCC: The exhibit titled “14b_PRIMUSNXT TestRep” indicates its corresponding test data applies to all models stated in the “Primus NXT Family Listing”, inferring that the requested FCCID also apply to all models shown on page 3 of the exhibit. The exhibit further defines all models as comprising of identical electronics, but notes that “T Devices” include an additional RF transceiver and an antenna within the header. Without corroborating test data for both versions of the technology, devices with distinctly different antenna configurations are not considered electrically identical and, per 47 CFR 15.31, require a composite application. Please clarify and update documentation accordingly.

   Response by applicant:
   All of the 17 listed models have the 64 kHz coil telemetry function which is identical. As explained above the report 14b_PRIMUSNXT TestRep shows the exemption of the certification procedure because of the 40 dB below 15.209 limits for the coil telemetry.
   The 13 models with “T”-identifier are additionally equipped with a Med Radio transmitter according to 95I and are subject of certification in that filing. The compliance with the rule part 95I shows the other report 14a_PRIMUSNXT test report.

9. FCC: For future reference, per KDB 449498, devices with transmitting power <1mW do not require SAR computational reporting. Also note that, per KDB 388624, TCBs can process applications for med radio implants when computation SAR is not included

   Response by applicant:
   Thanks for the comment. The option of TCB approval was discussed before submitting the project to the FCC. Because of the device is also subject to medical approval the confirmed qualified procedure was not changed, although possible. For future projects it will done the TCB way.