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To Whom It May Concern:

Respectfully,

Ron Consiglio
Engineer – Electrical

Request for Limited Modular Approval as per FCC part 15.

The wBTU is to be installed into fMRI medical scanners. It is impractical to test the wBTU while installed into such a large machine, therefore modular approval is being requested.

1. The modular transmitter must have its own RF shielding. This is intended to ensure the module does not have to rely upon the shielding provided by the device into which it is installed in order for all modular transmitter emissions to comply with Part 15 limits. It is also intended to prevent coupling between the RF circuitry of the module and any wires or circuits in the device into which the module is installed. Such coupling may result in non-compliant operation.

Invivo: The wBTU is fully shielded with a welded aluminum enclosure and a cover with RF gaskets that is secured by screws.

2. The modular transmitter must have buffered modulation/data inputs (if such inputs are provided) to ensure that the module will comply with Part 15 requirements under conditions of excessive data rates or over-modulation.

Invivo: Data inputs are fiber optic. There is no modulation input.

3. The modular transmitter must have its own power supply regulation. This is intended to ensure that the module will comply with Part 15 requirements regardless of the design of the power supplying circuitry in the device into which the module is installed.

Invivo: The wBTU is designed to run from a regulated external 5V source. The radio circuitry is powered from 3.3V on-board regulator. Excessive voltage at the input will not result in more RF power.

4. The modular transmitter must comply with the antenna requirements of Section 15.203 and 15.204(c). The antenna must either be permanently attached or employ a “unique” antenna coupler (at all connections between the module and the antenna, including the cable). Any antenna used with the module must be approved with the module, either at the time of initial authorization or through a Class II permissive change. The “professional installation” provision of Section 15.203 may not be applied to modules.

Invivo: The external antennas are connected by standard SMA connectors. Therefore Limited Modular Approval is being requested. Installation of the wBTU will be performed by factory trained personnel and will be integrated into specific medical equipment approved by Invivo. Invivo shall approve the location of the supplied antennas and transmitter (wBTU) on the medical equipment. Each unit is provided with the appropriate antennas required for installation in a kit form for assembly into the equipment.

5. The modular transmitter must be tested in a stand-alone configuration, i.e., the module must not be inside another device during testing. This is intended to demonstrate that the module is capable of complying with Part 15 emission limits regardless of the device into which it is eventually installed. Unless the transmitter module will be battery powered, it must comply with the AC line conducted requirements found in Section 15.207. AC or DC power lines and data input/output lines connected to the module must not contain ferrites, unless they will be marketed with the module (see Section 15.27(a)). The length of these lines shall be length typical of actual use or, if that length is unknown, at least 10 centimeters to insure that there is no coupling between the case of the module and supporting equipment. Any accessories, peripherals, or support equipment connected to the module during testing shall be unmodified or commercially available (see Section 15.31(i)).

Invivo: The wBTU shall demonstrate compliance.

6. The modular transmitter must be labeled with its own FCC ID number, and, if the FCC ID is not visible when the module is installed inside another device, then the outside of the device into which the module is installed must also display a label referring to the enclosed module. This exterior label can use wording such as the following: “Contains Transmitter Module FCC ID: XYZMODEL1” or “Contains FCC ID: XYZMODEL1.” Any similar wording that expresses the same meaning may be used. The Grantee may either provide such a label, an example of which must be included in the application for equipment authorization, or, must provide adequate instructions along with the module which explain this requirement. In the latter case, a copy of these instructions must be included in the application for equipment authorization.

Invivo: Labels have been provided with the application.

7. The modular transmitter must comply with any specific rule or operating requirements applicable to the transmitter and the manufacturer must provide adequate instructions along with the module to explain any such requirements. A copy of these instructions must be included in the application for equipment authorization. For example, there are very strict operational and timing requirements that must be met before a transmitter is authorized for operation under Section 15.231. For instance, data transmission is prohibited, except for operation under Section 15.231(e), in which case there are separate field strength level and timing requirements. Compliance with these requirements must be assured.

Invivo: The wBTU shall be tested under expected operating conditions. No specific operating requirements applicable to the transmitter are required.

8. The modular transmitter must comply with any applicable RF exposure requirements. For example, FCC Rules in Sections 2.1091, 2.1093 and specific Sections of Part 15, including 15.319(i), 15.407(f), 15.253(f) and 15.255(g), require that Unlicensed PCS, UNII and millimeter wave devices perform routine environmental evaluation for RF Exposure to demonstrate compliance. In addition, spread spectrum transmitters operating under Section 15.247 are required to address RF Exposure compliance in accordance with Section 15.247(b)(4). Modular transmitters approved under other Sections of Part 15, when necessary, may also need to address certain RF Exposure concerns, typically by providing specific installation and operating instructions for users, installers and other interested parties to ensure compliance.

Invivo: The wBTU shall comply with the RF exposure requirements.