Cadwell Wireless EEG Recorder FCC Cover Letter

Cadwell
909 N. Kellogg St.
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Date: 10 June 2009

RE: EA 780428

To whom it may concern,

This submission is an application for Grant Authorization for a wireless EEG Recorder which incorporates an off-the-shelf 802.11b/g wireless LAN module manufactured by Laird Technologies.

Wireless EEG Recorder description:

The Cadwell Wireless EEG Recorder is a diagnostic device that is used to measure and record Electroencephalographic signals and other physiological parameters for diagnostic use.

The recorder is used for long term data collection to aid in the diagnosis of various neurological and sleep disorders. The recorder is worn by a patient on a belt in a small pouch. Various data acquisition devices (EEG, nasal pressure, limb movement, body position, SPo2 etc.) are attached to the patient and connect to the recorder.

Recorded data is stored on a compact flash memory card and may sent by wireless connection if configured to do so. Downloaded data is reviewed by a physician or electrophysiologist.

If operating wireless, near real time data is captured on the host PC while patient is free to roam about the wing of the hospital (to recreation room, food, and bathroom).

Data is always stored on the compact flash, and is only transmitted wirelessly when an appropriate connection exists.

Note: The recorder is NOT used to monitor vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient. It is a diagnostic tool only.

Submission overview:

The Cadwell Wireless EEG Recorder incorporates the Laird/Euzrio WISMC01BI (FCC ID# PI405W) off-the-shelf 802.11b/g radio module. The Recorder uses the module's

internal on-board chip antenna. There is NO provision to connect an external antenna to the recorder.

The Ezurio module has limited single modular approval. Grant conditions state the module must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter. The Laird / Ezurio FCC grant is an attachment to this cover letter.

In order to leverage Laird/Ezurio's existing grant, additional testing over and above that performed by Laird/Ezurio was required.

The recorder will be located within 20 cm of the human body, so SARS testing was performed at RF Exposure Labs in Escondido, California. The Cadwell EEG Recorder with the Laird/Ezurio wireless module fell well within established safety limits. The SARS report is attached as an exhibit.

Additionally, unintended radiation testing was performed at CKC Laboratories in Bothell, Washington. The Cadwell EEG Recorder with Laird/Ezurio wireless module fell well under established limits. This report is also attached as an exhibit.

The additional tests Cadwell performed, along with testing performed by Laird/Ezurio to gain the original module grant, demonstrate that the system complies with FCC requirements for Cadwell's grant request.

Exhibit notes:

Block diagrams – Block diagrams are provided for the Laird/Ezurio WISMC01BI wireless module and for the Cadwell Recorder which contains the module.

External photos – External photos are self explanatory**.** Size, shape and appearance of the Recorder can be determined. The photos do not reflect the FCC label. However the planned label is submitted as a separate exhibit. The label will be placed on the back of the recorder where the prototype label is located in the photos.

ID Label / Location Info – This exhibit details the label on the Recorder. The exclamation (!) mark above the FCC ID number is a harmonized symbol used in the medical device industry. It cautions user to refer to the user manual for important information. This will lead the operator to the required FCC statements in the user manual. The statements in the user manual are a separate exhibit.

Internal photos – These photos depict the internal construction of the recorder so the component layout and assembly may be understood. Note that the Laird/Ezurio 802.11 radio module is located in the rounded end of the recorder. The module is located and spaced such that no matter how positioned relative to the body, radio module energy always stays well below required SARS levels. Refer to RF exposure attachment.

Operational Description – This exhibit describes the function of the Easy Wireless EEG Recorder

Schematics – These exhibits are schematics for the Cadwell Easy Wireless EEG Recorder and for the Laird/Ezurio WISMC01BI wireless module.

Test Reports – This exhibit contains report FC09-080 for Easy Wireless EEG Recorder unintended emissions performed by CKC Labs.

Test Setup Photos – Test reports from the RF Exposure Labs and CKC Labs contain test setup photos. No photos were supplied separately.

User Manual - This exhibit details the instructions that will be placed in the user manual. At this time the user manual is not completed. The actual manual will be supplied later if requested / required.

RF Exposure – This exhibit is the SARS testing report SAR.20090302 for the Cadwell Easy Wireless EEG Recorder with the Laird/Ezurio WISMC01BI wireless module.

Note: This is Cadwell's first FCC grant submission. We realize there may be additional information the FCC will require in order to complete the assessment. We will gladly provide any additional information.

Confidentiality: We request that certain exhibits in this submission be treated with confidentiality pursuant to Sections 0.457 and 0.459 to ensure competitors do not get a hold of critical Laird/Ezurio or Cadwell information to gain competitive advantage. Confidential files have been marked as such in the exhibit submission.

Respectfully,
Chris L Bolkan

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Attachment: Laird Ezurio radio module grant.