From: Michael Ellis

To: Leann Nguyen
Date: November 01, 2007

Subject: FCC File# 0024-EX-PL-2007

Message:

This is a response to questions from the FCC regarding reference number 5622. The Form 442 Confirmation Number is EL731911 and the Form 442 File Number is 0024-EX-PL-2007 for the CardioMEMs experimental license application.

The CardioMEMs system communicates with an implanted medical sensor and can span the frequency range of 30-42MHz. FCC approval under Part 18 has already been granted for this system in the 30-37.5MHz frequency range.

An individual implanted sensor may see pressure from 0-100 mmHg in gauge pressure which corresponds to a frequency bandwidth of approximately 2MHz. Although, most sensors will only see pressure excursions of 15 mmHg pulse pressure which corresponds to a frequency bandwidth of approximately 300kHz. Therefore a particular measurement from an implanted heart sensor is expected to use a bandwidth of 300KHz, within the 30-42MHz range, with emissions lasting only a few minutes, for the duration of the measurement.

The FDA mandates the number of clinical trials, as part of the FDA approval process. The clinical trials may have 40 centers with a total of 550 patients. CardioMEMs estimates that a limited number of these patients will have sensors in the 37.5-42MHz frequency range. CardioMEMs also estimates a limit to the number of patients (whose sensor operates outside the already licensed 30-37.5MHz frequency band) to be below 5% or approximately 25-30 patients that have sensors in the 37.5-42MHz range.

Approximately 5% of the implanted heart sensor fall in the 37.5-42MHz region, however this is a temporary situation until the manufacturing process for the heart sensor is refined so that only sensors in the allowed 30-37.5MHz range are produced.

Currently the CardioMEMs production of heart sensors is limited, therefore it becomes necessary to request an experimental license for temporary use of the full 30-42 MHz range in order to satisfy FDA requirements for the clinical trials.

CardioMEMs wants to emphasize that the use of the additional 37.5-42MHz region is strictly a temporary situation only for the duration of the clinical trials.

The CardioMEMs device has already been tested and complies with Part 18. Because of the limited power and occasional and temporary usage in the 37.5-42 MHz band, there should be no interference to other services in this band.

In the unlikely event of interference, CardioMEMs will take immediate corrective action, including rescheduling a particular trial at a different hospital, or using a shielded room to block interference.

CardioMEMs therefore requests that an experimental license be granted.