From: Michael Ellis

To: Leann Nguyen
Date: January 26, 2008

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

This is a progress report generated for the FCC regarding correspondence reference number 5904. The Form 442 Confirmation Number is EL731911 and the Form 442 File Number is 0024-EX-PL-2007 for the CardioMEMs experimental license application, which is currently pending approval.

The CardioMEMs system interrogator has already been approved under FCC part 18 for the 30-37.5 MHz range. The interrogator communicates with an implanted medical sensor. This experimental license is being requested to support a few implanted sensors, and therefore a few interrogators, that may operate in the 37.5-42 MHz range. This will be a temporary situation until the sensor manufacturing process is refined enough to manufacture all sensors to the approved 30-37.5 MHz region.

CardioMEMs has already begun clinical trials for heart failure, using the implanted sensors. The clinical trials are mandated and under the supervision of the FDA. An FDA approved feasibility trial was conducted with 13 patients, to show that the technology is viable. Pivotal trials are now in process, and have been performed on 42 patients. In the pivotal trial, the data, communicated by the implanted sensor to the interrogator, is actually used by the FDA and CardioMEMs to obtain statistical results that hopefully will qualify the technology for general medical use.

It has been fortunate in these clinical trials that all implanted sensors, and interrogator communications, have been within the range of the 30-37.5MHz spectrum that has already been approved by the FCC.

The pivotal trials will continue with another approximately 300 patients.
This experimental license, if granted, would support those few implanted heart sensors that may be in the 37.5 - 42MHz range.

CardioMEMs wants to emphasize that the use of the additional 37.5 ? 42 MHz region, if necessary, will strictly be a temporary situation only for the duration of the remaining clinical trials.

The CardioMEMs interrogator 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.