FCC bi-annual experimental license Report

File #: 0024-EX-PL-2007
Confirmation Number: EL731911

This is an updated progress report for the experimental license granted to CardioMEMs under confirmation number EL731911 and file number 0024-EX-PL-2007. This license is based on a previous license held by CardioMEMS under file number 0031-EX-PL-2003, which was authorized on February 25, 2003.

Because CardioMEMs is still in FDA mandated clinical trials, the information given in this progress report is very similar to the one submitted in Aug. 2009.

CardioMEMs technology is a significant advance in the state of the art in post operative non-invasive medical techniques for measuring various pressures within the human body. There are currently limited technologies for measuring pressure within the body and these technologies are usually not conducive with patient care management. CardioMEMs, we believe, is the first successful demonstration of using inductive techniques to measure pressure within the human body in a fashion not requiring an active implantable medical device. This technology allows the measurement of blood pressure and potentially other biological parameters that currently cannot be made with the same amount of ease and convenience to the patient and physician using current commercially available technology.

The system consists of two functionally independent systems; (a) an inductive system whose purpose is to power, via magnetic field coupling, a separate transmitting device(sensor) that has been implanted in an individual and (b) a communications system that provides a link from the sensor transmitter to a receiver located outside the human body.

For purposes of the current clinical trials, the inductive system used to power the sensor typically operates over a frequency range from 30-37.5 MHz. However, during the clinical trials, there could be situations which would require the use of a sensor outside this range. In fact, during the last six months, there have been six procedures that used a sensor in the 37.5-42MHz range.

CardioMEMs had already begun clinical trials for heart failure in 2007, using the implanted sensors. The clinical trials are mandated and under the supervision of the FDA. A FDA approved feasibility trial was conducted, in 2007, with 13 patients, to show that the technology is viable. At the time of the last report to the FCC in 2009, the wireless implant procedure had been performed, in clinical trials, on 512 patients in various locations in the United States. There were six instances in which a sensor transmitting in the 37.5-42 MHz range needed to be used. Even though trial implants were completed in 2009, it is still necessary to monitor the patients for a certain period of time, including the six patients whose sensor is in the 37.5-42MHz range.

Clinical trial documentation and evaluation are still in process. Even though the experimental license grants temporary permission to use the 37.5-42 MHz frequency range, the final sensors will be restricted to the range of 30-37.5MHz. CardioMems intends to maintain the experimental license only during the clinical trial phase of FDA feasibility procedures.