

PROPOSED EXPERIMENTAL OPERATION

Premise of the Experimentation.

AJ Medical Devices ("AJ Medical") herein supplements its application for new experimental authority with the following detailed information regarding its proposed operations. AJ Medical seeks authority to operate 36 unique Medical Implant Communications Service (MICS) devices. As intentional radiators, MICS devices are not permitted to operate under the Commission's rules, even for the purposes of testing and demonstration, absent an equipment authorization. Accordingly, AJ Medical herein seeks permanent experimental authority to permit it to operate the devices at commercial and residential environments with human and dog subjects in the states of Illinois and Minnesota as described below.¹

AJ Medical's request for experimental authority is supported by good cause. AJ Medical has entered a new phase in the development of a cardiac arrest monitor and alarm that detects ventricular fibrillation or asystole and transmits an alarm signal and ECG. The unit comprises of two elements. The first element is an implanted patient monitor containing a transceiver that transmits automatically in the event of a medical emergency, and by patient activation for non-emergency and system testing, to a second device, which is an external transceiver (pocket receiver) located within a few meters of the patient. The pocket receiver itself receives the transmission from the implant and, in return, transmits to it, for programming and for activating the implant's transmission in the patient activation mode. Clear channel access scanning is performed by the pocket receiver before it transmits to the implant to enable its transmission in the patient-activated mode.

AJ Medical herein seeks authority to use its medical implant and associated receiver devices for up to 24 months in clinical trials wherein patients will be ordered by their physicians to test the transmission through weekly magnet-activation of the implant's alarm function. AJ Medical will also be testing the devices in its laboratories and in medical facilities with dogs in order to gather additional feedback regarding system functionality and efficiency. The information garnered from the operation of these devices will permit AJ Medical to improve performance of the devices, enabling the company to continue to make modifications to its MICS chips before bringing them to full production.

¹ The Commission has previously authorized AJ Medical to operate its experimental devices on an STA basis. Owing to a re-commitment of its funding, AJ Medical is herein seeking permanent authority to operate its devices in a fashion nearly identical to its previously approved STA operations. (See File Nos. 0348-EX-ST-2005 and 0713-EX-ST-2005.)

The devices operate at extremely low power of just 25 uW. AJ Medical will be operating its devices only in the laboratory setting or under physician supervision at locations in Illinois and Minnesota.

AJ Medical is performing these experimental operations in anticipation of filing an application seeking authority under the Commission's equipment authorization rules in the future. Additionally, AJ Medical requires the feedback from its experimentation in order to supplement its applications before the Food and Drug Administration, which also must approve of the use of MICS devices. To this end, and given the incredible health benefits that are afforded from early detection of heart-related events, AJ Medical maintains that this request is in the public interest.

Details of operation:

AJ Medical is a manufacturer of MICS devices and seeks authority to test 36 unique devices in different environments: 12 devices are proposed for use in AJ Medical's laboratory facilities for testing; 12 devices will be used to transmit from dogs in medical facilities; and 12 devices will be used to transmit from human patients who will be working with their physicians in medical facilities and their respective residential environments. In all phases of use, the devices are operated on a single MICS frequency at extremely low transmitting power within a small radius around the body and worn against the body. Accordingly, and given the characteristics of the devices and the relatively small testing sample, AJ Medical asserts that there is no potential for interference with other devices in the adjacent spectrum.