K960849   510(k) Summary

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Background:

Cardiac Assist Devices, Inc. has design, developed, and extensively tested a device that is useful, safe and effective for forewarning presence of environmental magnetic fields that might be potentially harmful for certain individuals with implantable devices such as pacemakers or ICD's.

Motivation for the development of the Magno Alarm:

The motivation for developing the Magno Alarm was the fact that the pacemakers/ICD's are equipped with a magnetic field sensory mechanism that is an integral part of the device. This magnetic field sensory mechanism, within the pacemaker/ICD's, is intended for a non-invasive and non-contact mode alteration of the implantable device via a test magnet by and under supervision of a physician. Although this magnetic field sensory mechanism within the implantable devices offers a useful remote, non-invasive and non-contact access for mode alteration of the implantable device, however, it does not have any safeguard against inadvertent exposure to environmental magnetic field. In other words, if an individual whose heart's function depends on a pacemaker or an ICD is inadvertently exposed to a magnetic field of, say the refrigerator door seal, then the mode of his/her implanted device may change; such occurrence may be extremely harmful to the individual. To protect the individual with implanted heart assisting devices such as pacemakers/ICD's against accidental exposure to environmental magnetic fields, Cardiac Assist Device, Inc. has developed a device that has a lower activation threshold from that of typical pacemakers and/ or ICD's. The lower activation threshold of the Magno Alarm provides a safety factor of at least two (2) for the patient to get a warning regarding the presence of magnetic field in his/her environment. The warning of the Magno Alarm enables the patient to retrace his/her steps to safety, before the environmental magnetic field can cause an undesirable mode alteration of the implantable pacemaker/ICD. The Magno Alarm has been designed so that it does not interfere with the function of pacemakers/ICD's. The Magno Alarm is a device that in presence of magnetic fields produce sound and light signals to be noticed by the hearing and sight senses of an individual who is using it. In conclusion, the Magno Alarm is a safe, effective and useful device that enables a person to sense presence of environmental magnetic fields by producing audio and visual signals. The Magno Alarm is presented to be substantially equivalent to the test magnets employed as an external and non-contacting auxiliary tool for pacemakers/ICD's. Next section of this supplement presents the bases of the substantial equivalence of the Magno Alarm and the predicate device.

Bases of Substantial Equivalence:

a) The Magno Alarm is used to ascertain and verify the proper magnetic field environments for pacemakers/ICD users. The test magnet interacts with pacemakers/ICD's via the magnetic field. While the test magnet employs magnetic field to make pacemakers/ICD's to operate in a particular mode (the magnet mode), the Magno Alarm detects the magnetic field(s) that prevents the pacemakers/ICD's from operating in a particular mode (the normal mode)

b) Use of the test magnet generates information useful to the implantable pacemaker/ICD patients that is under the magnet mode. The pacemaker's pacing rate, under the test magnet, is an indication of the remained battery life of the pacemaker. Similarly, use of Magno Alarm generates information useful to the implantable pacemaker/ICD patients, that is, when the device (Magno Alarm) is not alarming, the environmental magnetic field is safe for the implantable pacemaker/ICD.

c) Both the test magnet and the Magno Alarm do not physically contact the implantable device while they perform their intended functions.

The Magno Alarm has been tested for electromagnetic compatibility and the test results is included in the supplement to our 510(k) (K960849) of 08-12-96.

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