

JAN 24 1993

K 943 657

510(k) Summary

Teletronics Pacing Systems 510(k) products: Leads, Pacers and Accessories

Summaries of Equivalence for 510(k) for life supporting, life sustaining and implantable devices. These summaries should:

Specify the device or devices to which the manufacturer is claiming equivalence to design, materials (for devices which are implants or which are designed to come into contact with the body), performance and indications.

The change in the contract sterilization company does not change the product performance characteristics and indications for use, and no new materials are used in the manufacture of the Company's products. Devices to which substantial equivalence is claimed is detailed in **Exhibit 7**.

If the "equivalent" old device is manufactured by the sponsor of the 510(k), discuss the reasons for each of the changes made and a description of any complications or possible adverse side effects related to the "equivalent" old device which led to the changes in the new device.

Cordis Corporation has announced that it will stop sterilizing at their facility as of October 1, 1993. In choosing another contract sterilizer, we have also decided to select a company that will sterilize with 100% EtO gas so that we may be in compliance with the upcoming EPA regulations by eliminating the use of an ozone depleting substance, such as Freon, from our process. Teletronics Pacing Systems has therefore, in conjunction with Cordis Corporation, selected and validated Griffith Micro Science, Inc., as the contract sterilizer. These changes are not related to any complications or adverse side effects.

Provide specific data to show that each of the changes is safe and effective.

The Documentation and data regarding the change to another contract sterilization company provided in this submission demonstrate that the change is safe and effective. This change is not being made as a result of any patient complications.

Include an update of the complications (as current as is presently known to the sponsor) and an update of all the clinical data to within three months of the submission.

Since there are no clinical trials, there have been no adverse effects and thus this portion is not applicable.