K963898

MEDTRONIC CONFIDENTIAL

# G: 510(K) SUMMARY

## 1. SUBMITTER'S NAME, ADDRESS

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JUL 22 1997

| | |
|---|---|
| **2. TRADE NAME:** | Bipolar temporary myocardial pacing wire, Model 6495 |
| Common Name:<br>Classification Name: | Temporary Pacing Lead<br>Temporary Pacemaker Electrode |
| Classification | This device has been classified by the Circulatory Systems Device Panel into Class II, (21 CFR 870.3680(a)). |
| **3. SUBSTANTIALLY EQUIVALENT DEVICE(S)** | Temporary Myocardial Pacing Wire, Medtronic Model 6500, marketed via K944957<br>Bipolar temporary Myocardial Heart Wire, Oscor Model TME 65 C, marketed via K850622 |

## 4. DEVICE DESCRIPTION

The bipolar temporary myocardial pacing wire, Model 6495 consists of a distal electrode, proximal electrode, and a coaxial conductor which are crimped together. A blue polypropylene fiber proximally coiled (flattened coil) for fixation of the lead is attached to the distal electrode and terminated in an atraumatic curved needle. An atraumatic breakaway chest needle at the other end of the conductor wire permits running the lead through the chest wall. Proximal to the chest needle is a connector ring crimped to the conductor wire.

After removal of the pacing wire, which is performed by gentle traction, no part of the wire remains in the body.

## 5. INDICATIONS FOR USE

The bipolar temporary myocardial pacing wire, Model 6495 is designed for temporary atrial and ventricular pacing and sensing, for a maximum of 7 days, during and after cardiac surgery. The Model 6495 is intended for single use only.

## 6. TECHNOLOGICAL CHARACTERISTIC COMPARISONS

The bipolar temporary myocardial pacing wire, Model 6495 is substantially equivalent to the following products:

- Unipolar temporary myocardial pacing wire, Medtronic Model 6500, marketed via K944957
- Bipolar temporary myocardial heart wire, Oscor Medical Corporation Model TME 65 C, marketed via K850622

The table below contains a comparison of the similarities and differences of the Model 6495 to the predicate devices to which it is substantially equivalent. Similarities between the Model 6495 and the comparison devices are noted.

The bipolar temporary myocardial pacing wire, Model 6495 contains technologies comparable to Medtronic, Inc. temporary myocardial pacing lead, Model 6500. The proximal end of the Model 6495 ends in a straight chest needle, similar to the Model 6500. The conductor wire material is stainless steel, identical to that of the Model 6500 and the Oscor Model TME 65 C. The insulation materials for the Model 6495 are identical to the Model 6500 and the Model TME 65 C. The distal end is identical to the Model 6500, and similar to the Model TME 65 C. The Model 6495 utilizes the double pouch package configuration, identical to that utilized by the Model 6500. The Model 6495 uses the same 100% EtO sterilization process as the Model 6500. The Model 6495 is a bipolar heartwire, as is the Model TME 65 C myocardial heartwire.

| **Manufacturer** | **Medtronic** | **Oscor Medical** | **Medtronic** |
|---|---|---|---|
| **Model No.** | 6495 | TME 65 C | 6500 |
| **510(k) Number** | | K850622 | K944957 |
| **Intended Use** | Temporary Myocardial Pacing and Sensing | Same | Same |
| | Bipolar | Bipolar | Unipolar |
| **Electrode** | Two discrete electrodes | Ring electrode and wire | Tip |
| **Electrode and Conductor Material** | Stainless Steel | Same | Same |
| **Fixation Mode** | "Pigtail" Coil | Zigzag and suturing | "Pigtail" Coil |
| **Outer Insulation Material** | Polyethylene | Same | Same |
| **Insulated Wire Diameter (nominal)** | 0.7mm | 0.45 mm | 0.7mm |
| **Proximal Needle Shape and Breakaway Feature Size (nominal)** | Straight<br>Breakaway<br>L = 88mm<br>D = 1.0mm | Slightly curved<br><br>L= 80mm<br>D = 1.12 mm | Straight<br>Breakaway<br>L = 90 mm<br>D = 1.0 mm |
| **Distal Needle Shape Size (nominal)** | 3/8<br>Curved<br>L = 32mm<br>D = 0.38mm | 1/2<br>Curved<br>L = 16mm<br>D = 0.52 mm | 3/8<br>Curved<br>L = 25mm<br>D = 0.66mm |
| **Sterile Package Configuration** | Blister/Pouch | Pouch/Pouch | Blister/Pouch |
| **Sterile Packaging Materials** | spunbounded olefin-PE/Polyester | not known | spunbounded olefin -PE/Polyester |
| **Sterilization & Aeration Process** | 100% EtO | not known | 100% EtO |

## 7. SUMMARY OF STUDIES

Medtronic, Inc. performed device integrity testing to support the bipolar temporary myocardial pacing wire, Model 6495 is substantially equivalent to the predicate devices.
Device integrity testing included:

- Visual verification
- X-ray & Dimensional verification
- Electrical verification
- Pull strength verification
- Flex life verification
- Connector compatibility
- Break moment of thorax needle

All device integrity test results for the bipolar temporary myocardial pacing wire, Model 6495 met specified requirements.

## 8. CONCLUSION (STATEMENT OF EQUIVALENCE)

Through the data and information provided in this submission, numerous similarities support a substantial equivalence determination, and, therefore, clearance of the 510(k) notification for the bipolar temporary myocardial pacing wire, Model 6495.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Susan Noddin
Product Regulation Manager
Medtronic, Inc.
7000 Central Avenue, N.E.
Minneapolis, Minnesota 55432-3576

JUL 22 1997

Re: K963898
Model 6495 Bipolar Temporary Pacing Lead
Regulatory Class: III (three)
Product Code: LDF
Dated: April 24, 1997
Received: April 25, 1997

Dear Ms. Noddin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATIONS FOR USE

The Model 6495 bipolar temporary myocardial pacing lead is designed for temporary atrial and ventricular pacing and sensing, for a maximum of 7 days, during and after cardiac surgery. The Model 6495 bipolar temporary myocardial pacing lead is intended for SINGLE USE ONLY.

(Division Sign-Off)
Division of Cardiovascular, Respirato
and Neurological Devices
510(k) Number K963898