

K970347
Aug 29, 1997

510(k) SUMMARY

SUBMITTER:

Submitted on behalf of:

Medical Pacing Concepts, Ltd.
Suite 934 Twelve Oaks Center
15500 Wayzata Blvd.
Wayzata, MN 55391

Telephone: (612) 449-9304
Facsimile: (612) 476-7464

By:

Paladin Medical, Inc.
P.O. Box 560
Stillwater, MN 55082

Telephone (715) 549-6035
Facsimile: (715) 549-5380

CONTACT PERSON:

Elaine Duncan
President, Paladin Medical, Inc.

DATE SUMMARY PREPARED: January 15, 1997

TRADE NAME:

MPC 7000 External Temporary Pacemaker System

COMMON NAME:

External Temporary Pacemaker

SUBSTANTIALLY EQUIVALENT TO: Pace Medical, Inc. Model 4542 External
Pulse Generator (K821791)

DESCRIPTION OF THE DEVICE:

The MPC Model 7000 External Temporary Pacemaker System is a battery powered, single chamber external pacemaker. It consists of two major components: the MPC Model 3000 Programmer and the MPC Model 1000 Pulse Generator. The System also includes an MPC Model 5003 Patient Arm/Leg Strap used to secure the Pulse Generator to either the patient's arm or leg. An MPC Model 5002 Programmer Holder to store the Programmer on a wall is also available.

The MPC Model 3000 Programmer transmits the pulse programming data selected by the physician for patient therapy to the MPC Model 1000 Pulse Generator by infrared telemetry.

The MPC Model 1000 Pulse Generator and the MPC Model 3000 Programmer are re-usable. The MPC Model 1000 Pulse Generator and the MPC Model 3000 Programmer are designed so that they may be disinfected between patient use. The MPC Model 5003 Patient Arm/Leg Strap is disposable and labeled for single-use only.

INDICATION FOR USE:

The MPC Model 7000 External Temporary Pacemaker System is indicated for temporary (1-10 days typical) ventricular cardiac pacing in a controlled clinical environment.

INTENDED USE:

Typical clinical applications include the management of pre-operative, intra-operative and post-operative management of cardiac surgery patients, short-term treatment of arrhythmia and heart block and emergency cardiac pacing.

CLINICAL INFORMATION:

Typical clinical applications include the management of pre-operative, intra-operative and post-operative management of cardiac surgery patients, short term treatment of arrhythmias and heart block and emergency cardiac pacing. Temporary external pacing has been shown to be safe and effective for these indicated uses. The MPC Model 7000 External Temporary Pacemaker System incorporates the same basic performance parameters as comparable products used in hospitals for more that three decades. The main difference of the MPC Model 7000 Pacemaker System is that it is ergonomically configured to improve

77

patient safety, comfort and the product's ease of use by reducing the size of the Pulse Generator to a wearable size.

SUMMARY OF SAFETY AND EFFECTIVENESS TESTING:

The MPC Model 7000 External Temporary System is substantially equivalent to the Pace Medical, Inc. Model EV 4542 External Pacemaker. Tests show that differences due to the ergonomic design features do not introduce different safety issues. The Technical and Clinical Manuals, as well as product labeling, should be used as a guide to the safe operation of the MPC Model 7000 External Temporary Pacemaker System.

STATEMENT OF SUBSTANTIAL EQUIVALENCE:

Medical Pacing Concepts, Ltd. considers the MPC Model 7000 External Temporary Pacemaker System to be substantially equivalent to the Pace Medical, Inc. Model EV 4542 External Pulse Generator (K821791).

SUMMARY OF WHY DIFFERENCES DO NOT AFFECT SAFETY:

The differences between the Pace Medical, Inc. Model EV 4542 and the MPC Model 7000 External Temporary Pacemaker System are differences which enhance the use and patient interface, patient safety and patient comfort.

The most significant improvements made in the MPC Model 7000 External Temporary Pacemaker System as compared to the Pace EV 4542, is the weight and size of the Pulse Generator. The controls (a separate Programmer) have been separated from the Pulse Generator.

The miniaturization and separation of the Pulse Generator from the Programmer allow the physician to position the Pulse Generator in the most advantageous location to provide protection to the lead. One of the major complications to external pacemakers is inadvertent lead disconnection. The wearable feature of the MPC Model 7000 reduces the risk of lead pull-out by minimizing the opportunity for the lead to become entangled in bedding and monitoring lines. The wearable feature and the greater range of motion by the patient will also enhance patient comfort.

Separation of the controls, in the form of a Programmer, from the Pulse Generator, prevents inadvertent operation by the patient or visitors. Physicians are familiar with



separate Programmers and Pulse Generators for implantable units, so the separation of the Pulse Generator from the Programmer does not introduce a new safety issue.

The Pulse Generator is safely programmed through the use of an infrared telemetry link. This design allows the user to verify the data being programmed on the Programmer Liquid Crystal Display (LCD) prior to transmission and again on the Pulse Generator LCD upon the data being received.

The software is confined to the Programmer component, thus allowing the Pulse Generator electronics to be greatly simplified. This enhances the reliability and safety of the Pulse Generator, which is the more critical component of the two because of its being connected directly to the patient and delivering the patient treatment.

Further safety features include several checks and balances within the system design and function prior to the patient's receiving treatment. For example, the infrared communication link is one-way. The one-way communication takes place from the Programmer to the Pulse Generator. Before the selected settings are sent to the Pulse Generator, the physician visually verifies the programmed settings values by viewing the LCD on the Programmer. All parameters allowed by the software are within nominal ranges for external pacemakers.

After the Pulse Generator has been programmed to the specified setting or settings, the physician may again reconfirm the settings by viewing the LCD on the Pulse Generator. If desired, this can be done with the Pulse Generator in the OVO, non-pulsing position. This will allow the physician to take a third look at the settings prior to the patient receiving any treatment.

The separation of the Pacemaker into the Pulse Generator (PG) and Programmer requires two separate batteries for the MPC 7000 System instead of just one battery required for the Pace Medical EV 4542. The PG battery is a permanent, non-replaceable, implantable-grade battery, selected for long-life performance. The PG case is sealed, with no serviceable internal parts. Operators are instructed to return the PG when the low battery (BAT) condition is indicated. The Programmer also indicates when the battery power is low. This battery is replaceable.

A key additional feature of the MPC Model 7000 External Pacemaker System is the fact that the Pulse Generator is significantly protected from cellular phone interference. Specially designed shielding protects the Pulse Generator from electromagnetic interference generated by cellular phones.

MPC conducted extensive qualification and validation for the MPC 7000 External Temporary Pacemaker and Accessories. The testing protocols and results show that the PC

75

Model 7000 External Temporary Pacemaker System and Accessories do not introduce any new issues of safety when compared to the Pace EV 4542 External Pacemaker. Furthermore, the unique features and improved ergonomics of the MPC Model 7000 significantly enhance patient safety considerations.

Telemetry was performed under a variety of lighting conditions in a clinical setting with various clinical equipment in use, as detailed in the Clinical Environmental Test. A transmitting range of between 2-15 inches allows placing the Programmer in close proximity to the Pulse Generator for successful data transmission under ambient light.

Extensive Electromagnetic Compatibility (EMC), Electromagnetic Interference (EMI), and Safety testing was conducted on the MPC Model 7000 External Pacemaker System to document that this system operated safely and to specification in an environment with potential electromagnetic challenges. The MPC Model 7000 External Temporary Pacemaker passed these EMC/EMI/Safety and Defibrillation Tests.

The MPC Model 7000 External Temporary Pacemaker System was tested for radiated emissions and passed this test.

The MPC Model 7000 External Temporary Pacemaker System was Drop Tested and Ship Tested and passed these tests.

The MPC Model 7000 External Temporary Pacemaker System's software has been validated and tested.

Cleaning and disinfection described in the Instructions for Use have been validated for the MPC Model 1000 Pulse Generator and MPC Model 3000 Programmer.

The MPC Model 5003 Patient Arm/Leg Strap has been tested and determined to be biocompatible and non-cytotoxic.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 1997

Ms. Elaine Duncan
President, Paladin Medical, Inc.
for Medical Pacing Concepts, Ltd.
P.O. Box 560
Stillwater, Minnesota 55082-0560

Re: K970347
Trade Name: MPC Model 7000 External Temporary Pacemaker System
and Accessories
Regulatory Class: III
Product Code: 74DTE
Dated: May 30, 1997
Received: June 3, 1997

Dear Ms. Duncan:

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 (Pre-market 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market 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.

Page 2 - Ms. Elaine Duncan

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 "dsmo@fdadr.cdrh.fda.gov".

Sincerely yours,



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

Enclosure



510(k) Number (if known) K970347

Device Name: MPC Model 7000 External Temporary Pacemaker System

Indications for Use:

The MPC Model 7000 External Temporary Pacemaker System is indicated for temporary (1-10 days typical) ventricular cardiac pacing in a controlled clinical environment.

(Please Do Not Write Below This Line-Continue On Another Page If Needed)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X

OR

Over -The-Counter Use _____

(Optional Format 1-2-96)

Debra Telhi

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K970347