K002603

JAN - 8 2001

APPENDIX 10

510(K) SUMMARY

Submitted by:
Zynergy CardioVascular, Inc.
298 Fernwood Ave.
Edison, NJ 08837

August 18, 2000

This 510(k) Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Contact Person:

Ms. Jing Zhang
Manager, Regulatory Affairs/Quality Assurance
Zynergy CardioVascular, Inc.
298 Fernwood Ave.
Edison, NJ 08837
Phone: (732)225-3800 Fax: (732)225-4454

2. Device Name and Classification:

- Trade name: Zynergy BalloonPace Balloon Guided Pacing & Monitoring Catheter
- Common / Usual Name: Transvenous Pacing Catheter
- Classification Name: LDF - Electrode, Pacemaker, Temporary, CFR 870.3680
- DYG - Catheter, flow directed, CFR 870.1240
- Classification Panel: Cardiovascular
- Device Class: Class II

3. Substantial Equivalence:

The Zynergy BalloonPace Balloon Guided Pacing & Monitoring Catheter is substantially equivalent to the following two predicate devices:

1) *Elecath Balectrode Flow-Directed Pacing Catheter*
   Electro-Catheter Corporation
2) *Arrow Bi-Polar Temporary Pacing Balloon Catheter*
   Arrow International.

4. Device Description:

The BalloonPace catheter was designed and tested in accordance with the applicable sections of ISO 10555-1:1995, Sterile, Single-Use Intravascular Catheters - Part 1: General Requirements.

The BalloonPace catheter is comprised of a radiopaque PVC main body tube with two platinum electrodes and a latex balloon attached on distal end and a molded polyurethane junction on the proximal end which provides attachment for lead wire assemblies and balloon lumen access. The tubing is 5Fr in diameter. The electrode length is 5mm and electrode spacing is 1 cm. There are wires on the inside of the catheter making contact between the electrodes and the lead wire assemblies. Each catheter has a safety retainer cable attached to the cap electrode and anchored to the polyurethane junction. The proximal connectors have shrouded pins that meet the Performance Standard for Electrode Lead Wires and Patient Cables. Various curve styles are available in order to meet anatomical constraints and/or physician preference.

The product is packaged individually with a volume limited syringe as a single use disposable device and shipped ETO sterilized.

5. Intended Use of the Device:
The Zynergy BalloonPace Balloon Guided Pacing & Monitoring Catheter is intended for use in temporary transvenous ventricular cardiac pacing and monitoring as in the management of impaired impulse formation or conduction.

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:
The Zynergy BalloonPace Balloon Guided Pacing & Monitoring Catheter has similar technological characteristics as the predicate devices. They all are bipolar balloon guided pacing catheters with a cap electrode and a balloon at the distal end and two pin leads at the proximal end. Electrodes are all made of platinum and have the same length. The intended anatomical location of the distal end for all three catheters is the same: right ventricle. All three devices have the same "J" tip curve style. They are all radiopaque and are all packaged with a volume limited syringe. They are all ETO sterile, single patient use devices. The BalloonPace catheter is made of the same material, has the same elctrode spacing, and have the same catheter length as the Elecath catheter. The BalloonPace catheter has the same product range and same balloon inflation capacity as the Arrow catheter.

The differences between the BalloonPace catheter and the predicate devices in electrode cable design do not raise any new issues of safety or effectiveness as demonstrated by the comparable results of the functional and performance testing.

7. Tests and Conclusions:
Extensive functional and performance testing, and biocompatibility testing were conducted to assess the safety and effectiveness of the Zynergy BalloonPace Balloon Guided Pacing & Monitoring Catheter. All results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2001

Ms. Jing Zhang
Zynergy CardioVascular, Inc.
298 Fernwood Avenue
Edison, NJ 08837-3839

Re: K002603
Zynergy BalloonPlace Balloon Guided Pacing & Monitoring Catheter
Regulatory Class: II (two)
Product Code: 74 LDF
Dated: November 7, 2000
Received: November 8, 2000

Dear Ms. Zhang:

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 legally marketed predicate 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX 8
INDICATIONS FOR USE

510(k) Number (if known): K002603

Device name: Zynergy BalloonPace Balloon Guided Pacing & Monitoring Catheter

Indications For Use:

Zynergy BalloonPace Balloon Guided Pacing & Monitoring Catheter is indicated for use in temporary transvenous ventricular cardiac pacing and monitoring as in the management of impaired impulse formation or conduction.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR Over The Counter Use** _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002603 (Optional Format 1-2-96)