APR - 6 2000

K991060

Zcv

Zynergy CardioVascular, Inc.
298 Fernwood Avenue
Edison, NJ 08837-6803
USA
Tel: (732) 225-3800
Fax: (732) 225-4454

Safety & Effectiveness Summary: Zynergy Zolution Electrophysiology Catheter with Zyp Lok Accessory Cable

Classification Name: 74 DRF Catheter, Electrode Recording, CFR 870.1220

Common / Usual Name: Electrode Recording Catheter

Contact: Priscilla Whitehead Cox, Regulatory Affairs Manager

Prepared: Monday, March 29, 1999

The Zynergy Zolution Electrophysiology Catheter is intended as a primary diagnostic tool for intracardiac electrogram recording and pacing, for the determination of conduction times from one location to another, to identify aberrant conduction pathways and to assess arryhthmia vulnerability of the cardiac chambers.

Initial sizes to be marketed are 5Fr and 6Fr which include electrode lengths of 1-5mm, electrode spacing of 1mm -1cm and varying in the number of electrodes per catheter of 2 - 20. Various curve styles are available in order to meet anatomical constraints and/or physician preference. The Zynergy Zolution, Zyp-Lok Accessory Cable is a reusable, medical grade cable assembly available in lengths of 18", 36" and 72" and 4, 10 & 20 conductor configurations.

Zynergy Zolution Electrophysiology Catheter and Zyp-Lok Accessory Cable are supplied sterile in single use pouches. Zynergy Zolution Electrophysiology Catheter and Zyp-Lok Accessory Cable are supplied sterile in single use pouches. The packaged product is ETO sterilised with a sterility assurance level of 10^{-6}. Ethylene oxide residuals and bacterial endotoxin levels are monitored for compliance with ISO/FDA guidelines.

Performance testing including tensile, engagement, electrical resistance, electrical impedence and torque transmission was successfully completed.

Biocompatibility testing, including cytotoxicity, systemic injection, intracutaneous injection, hemolysis, complement activation, unactivated partial thromboplastin time assay, Lee White Clotting Time, pyrogenicity, mutagenicity, intravenous toxicity, sensitisation and implantation has been successfully completed per ISO10993 and FDA guidelines.

Zynergy Zolution Electrophysiology Catheter is similar in design, composition and function to the *Elecath Detector Series* 510(k)# K933450, manufactured by Electro-Catheter Corporation and the *Arrow Intracardiac Electrode Catheter Products*, 510(k)# K953651 manufactured by Arrow International.

COMPARATIVE FEATURES			
Characteristics	**ZCV, Inc Zynergy Zolution Electrophysiology Catheters**	**Electro-Catheter Co. Detector Series Electrophysiology Catheters**	**Arrow International Intracardiac Electrode Catheter Products**
Distal Tip Design	Soft, non-braided, atraumatic tip	Soft, non-braided, atraumatic tip	Soft, non-braided, atraumatic tip
Tip Curve Styles	Courmand, Josephson, Damato, Straight	Courmand, Josephson, Damato	Courmand, Josephson, Damato, Straight
Tubing Materials	Polyamide TPE / SS Wire Braid	Polyamide TPE / SS Wire Braid	Polyurethane
Electrode Materials	Platinum	Platinum	Gold/Platinum
French Size	3/5/6	5/6	2/5/6
Electrode Spacing	1-10mm	1-10mm	1-10mm
Connector Type	Positive Locking Multi-Pin	Positive Locking Multi-Pin	Positive Locking Multi-Pin
Tip Electrode length	2-5mm	2-5mm	Not specified
Electrode Number	2-20	2-10	2/4/6/10
Proximal Electrode Length	1-5mm	1-5mm	Not specified
Useable Length	110cm	110cm	110cm
Extension Cable	18"/3'/6'	3'/6'	18"/3'/6'
Packaging	Blister/Poly/Tyvek	Blister/Poly/Tyvek	Blister/Poly/Tyvek
Sterilisation Method	ETO	ETO	ETO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 6 2000

Ms. Priscilla Whitehead Cox
Zynergy CardioVascular, Inc.
298 Fernwood Ave.
Edison, NJ 08837

Re: K991060
Zynergy Zolution Electrophysiology Catheter Model Z5000 and Cable Model Z9000
Regulatory Class: II (two)
Product Code: DRF
Dated: January 21, 2000
Received: January 24, 2000

Dear Ms. Cox:

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" (21CFR 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,
Respiratory and Neurological
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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Enclosure

510(k) Number (if known): K991060

Device Name: Zynergy Zolution Electrophysiology Catheter with Zyp-Lok Extension Set

Indications For Use:

Zynergy Zolution Electrophysiology Catheter with Zyp-Lok Extension Set is intended for temporary use in electrophysiology studies for intracardiac stimulation and/or ECG recording.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number _____

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

(Optional Format 1-2-96)