SEP 3 1999

K990689

ZCV

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

Safety & Effectiveness Summary: Zynergy Loc-Sure Single Pass Drainage Set

Classification Name: 74DQY Catheter, Percutaneous

Common / Usual Name: Fluid Drainage Catheter

Contact: Priscilla Whitehead Cox, Regulatory Affairs Manager

Prepared: Tuesday, March 02, 1999

Zynergy Loc-Sure Single Pass Drainage Set is a minimally invasive device for percutaneous drainage of cysts, abcesses and fluid collections such as renal cysts; renal, hepatic and other abcesses; pleural effusions; ascitic/thoracic collections and nephrostomies.

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The Zynergy Loc-Sure Single Pass Drainage Set comprised of four components:

1. A radiopaque, semi-coiled, drainage catheter. The distal segment of the catheter has drainage holes on the inside radius to facilitate the draining of fluid from the selected body cavity.
2. The proximal connector cannula flange is comprised of a standard male luer lock. This is inserted into the catheter tubing and is used as an insertion guide for a trocar stylet and may be attached directly to ancillary drainage devices.
3. The trocar stylet is a needle used as a puncture trocar for placing the drainage catheter in the precise location required for the drainage procedure.
4. A suture button is included which may be sutured to the skin for safe extended drainage.

Zynergy Loc-Sure Single Pass Drainage Set is supplied sterile in single use pouches. Qualification is based on the overkill method with a sterility assurance level of 10^{-6}. The packaged product will be ETO sterilised in accordance with ANSI/AAMI/ISO 11135, *Medical Devices - Validation & Routine Control Of Ethylene Oxide Sterilisation*; EN550:1994, *Sterilisation of Medical Devices - Validation And Routine Control Of Sterilisation By Ethylene Oxide*; EN556:1994, *Sterilisation of Medical Devices - Requirements For Terminally Sterilised Devices To Be Labelled "Sterile"*. ETO residuals are within ISO10993-7 guidelines fo rprolonged exposure. Lal testing is done for each sterilzation lot to assure non-pyrogenicity.

Performance testing was successfully completed per BS/ EN1617: 1997.

Biocompatibility testing, including cytotoxicity, systemic injection, intracutaneous injection, pyrogenicity,sensitisation and implantation has been successfully completed per ISO10993 and FDA guidelines.

Zynergy Loc-Sure Single Pass Drainage Set is similar in design, composition and function to the *Elecath One-Step Fluid Drain Assembly* manufactured by Electro-Catheter Corporation and the *Dawson Mueller Drainage Catheter with Slip-Coat Hydrophillic Coating* manufactured by Cook.

COMPARATIVE FEATURES

Characteristics	**ZCV, Inc** *Zynergy Loc-sure Single Pass Drainage Set*	**Electro-Catheter Co.** *Elecath One Step Fluid Drain Assembly*	**Cook** *Dawson-Mueller Drainage Catheter with Slip-Coat Hydrophilic Coating*
Composition	Polyethylene	Polyethylene	Polyurethane with hydrophillic coating
Components	Catheter, SS cannula, trocar stylet, suture button, locking hub	Catheter, SS cannula, trocar stylet, retention flange, locking hub	Catheter, SS cannula, flexible cannula, trocar stylet, locking hub
Indications For Use	Renal cysts; renal, hepatic and other abcesses; pleural effusions; ascitic / thoracic collections and nephrostomies	Abcesses, cysts, other localised fluid collection; pleural effusions, ascitic fluid collections, renal cysts; renal, hepatic, subhepatic and subdiaphragmatic abcesses	Abcesses, cysts, other localised fluid collection; pleural effusions, ascitic fluid collections, renal cysts; renal, hepatic, subhepatic and subdiaphragmatic abcesses
Packaging	Poly/Tyvek	Poly/Tyvek	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

SEP 3 1999

Ms. Priscilla Whitehead Cox
Manager, Regulatory Affairs
Zynergy CardioVascular, Inc.
298 Fernwood Avenue
Edison, NJ 08837-3839

Re: K990689
Zynergy Loc-Sure Single Pass Drainage Set
Dated: June 7, 1999
Received: June 8, 1999
Regulatory Class: II
21 CFR §876.5130/Procode: 78 LJE

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) 594-4613. 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990689

Device name: Zynergy Loc-Sure Single Pass Drainage Set

Indications For Use:

Zynergy Loc-Sure Single Pass Drainage Assembly is a minimally invasive device for percutaneous drainage of cysts, abcesses and fluid collections such as:

- Renal cysts
- Renal, hepatic and other abcesses
- Pleural effusions
- Ascitic collections
- Thoracic collections
- Nephrostomies

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990689

(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)

(Optional Format 1-2-96)