Section II - Summary of Safety and Effectiveness

(1) Contact Information

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(2) Company Information

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(3) Device Name

Endocare Percutaneous Access Set

(4) Device Description

The Endocare Percutaneous Access Set is designed for use with the CRYOcare™ Surgical System during urological cryosurgery. The set is used to establish a one-pass percutaneous tract into the prostate for CRYOprobe™ placement. Each set includes a minimum of one stainless steel trocar stylet, one Teflon®-coated stainless steel dilator and one Teflon® introducer sheath. A thumb ring is incorporated into the stylet and the dilator includes a finger bridge for ease of use.

The access set is intended for one-time use and is packaged in a plastic tray and sealed pouch. Depending on the needs of the physician, the sets will be available in different packaging configurations with varying quantities of components (e.g., one to eight) to establish multiple percutaneous access tracts.

(5) Indications for Use

The Endocare Percutaneous Access Set is designed for use with the CRYOcare™ Surgical System for one-pass percutaneous placement of the CRYOprobes™ into the prostate during urological cryosurgery.

(6) Name of Predicate or Legally Marketed Device

Cook® Urological Onik-Cohen Percutaneous Access Set

(7) Substantial Equivalence

The Endocare Percutaneous Access Set is substantially equivalent to the Cook® Urological Onik-Cohen Percutaneous Access Set. The Onik-Cohen Percutaneous Access Set was determined to be substantially equivalent on July 9, 1993 (reference K930608). The Endocare device has similar indications for use and technological characteristics as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2000

Mr. Vincent Cutarelli
Sr. Vice President, Regulatory Affairs
and Quality Assurance
Endocare, Inc.
7 Studebaker
Irvine, CA 92618

Re: K002396
Endocare Percutaneous Access Set
Dated: July 27, 2000
Received: August 7, 2000
Regulatory Class: II
21 CFR §876.5130/Procode: 78 KOD
21 CFR §878.4350/Procode: 79 GEH

Dear Mr. Cutarelli:

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) 594-4639. 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications For Use

510(k) Number: K002396

Device Name: Endocare Percutaneous Access Set

Indications for Use: The Endocare Percutaneous Access Set is designed for use with the CRYOcare™ Surgical System during urological cryosurgery. The set is used to establish a one-pass percutaneous tract into the prostate for CRYOprobe™ placement.

Concurrence of CDRH, Office of Device Evaluation (ODE):

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002396

Prescription Use: X
(Per 21 CFR 801.109)