k973364
1 of 2

510(k) Summary of Safety and Effectiveness

NOV 26 1997

September 4, 1997

Submitted by: VidaMed, Inc.
46107 Landing Parkway
Fremont, CA 94538
Contact: Robin Bush
Phone: (510) 492-4930
FAX: (510) 413-1538

Product: Cobra Hand Piece

Common Name: Electrosurgical Device

Intended Use

The Cobra Hand Piece presented in this submission is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.

Device Description

The Cobra Hand Piece delivers the energy from the VidaMed TUNA System RF Generator. The Cobra Hand Piece contains two needle electrodes which are deployed at an angle of 90°. The needles can be deployed at 4 preset lengths which vary between 10-22mm. The needles are insulated at the base to protect the urethra during ablation of the prostatic tissue. The disposable Cobra Cartridge is attached to a reusable handle, containing the mechanism for the needle deployment and retraction. The Cobra Hand Piece only works with the VidaMed TUNA System RF Generator.

Technological Characteristics

VidaMed currently markets the TUNA Catheter as a disposable device. The Cobra Hand Piece represents a modification to the existing TUNA Catheter by creating a disposable cartridge that fits on the reusable handle. The cartridge will be manufactured with materials that are used currently in the TUNA device. The handle will be made of stainless steel, and is reusable to facilitate cleaning and sterilization.

Sterilization

The Cobra Cartridge is provided sterile and ready to assemble into the handle. The Cobra Handle is provided non-sterile and must be sterilized prior to use. The handle may sterilized by a variety of methods.

Substantial Equivalence

VidaMed's TUNA System and RF Generator have been cleared for the treatment of symptomatic BPH in several 510(k)s. The Cobra Hand Piece is a modification to the existing TUNA Cathether Hand Piece and shares similar features and function with corresponding devices distributed by VidaMed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 1997

Robin Bush, RAC
Vice President, Regulatory and
Clinical Affairs
VIDAMED
46107 Landing Parkway
Fremont, CA 94538

Re: K973366
VidaMed Cobra Hand Piece
Dated: September 4, 1997
Received: September 8, 1997
Regulatory Class: II
21 CFR 876.4300/Procode: 78 KNS

Dear Ms. Bush:

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 (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 requirement, 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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): N/A

Device Name:

Cobra Hand Piece

Indication for Use:

The Cobra Hand Piece presented in this submission is intended for the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostate sizes between 20 and 50 cc.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973366

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)