5/5/99

MAXXIM MEDICAL

510(k) Number: K984189

510(k) SUMMARY

Trade Name: Argon Multi-Lumen Central Venous Catheter

Common Name: Multi-lumen Catheter

Classification Name: Intravascular Catheter (per CFR 21 Part 880.5200)

Product Code: FOZ

Classification: Class II

Submitted by:
Maxxim Medical
Argon Division
1445 Flat Creek Road
Athens, Texas 75751
Phone: 903-675-9321
Fax: 903-677-9397

Contact person: Eddie Monroe, VP QA/RA

Date prepared: November 17, 1998

Legally marketed device to which equivalence is claimed:

Medex *Safe*-Cath K960764

Description of Device:

The Argon multi-lumen central venous catheter has a polyurethane body with multiple lumens. There can be from two through five lumens. ~~Diameters will be from 4 French through 12~~ The size of the catheter is 7-8 French and lengths 10 cm through 30 cm. Each lumen extends from the vicinity of the distal tip to the main (bifurcation) hub, where it branches into dedicated

extension lines. The largest lumen extends all the way to the distal tip. It is used for device placement using a guide wire and then to infuse fluids. The other lumens exit the catheter body at side ports that are near the distal tip but are at varying distances proximal to the tip. Functionally, the lumens are used to measure central venous pressure, to sample venous blood and to infuse parenteral nutrition (TPN) or medications. With multiple lumens more than one function can be accomplished for the patient at the same time.

When a side port is not actively being used a saline drip is run to prevent thrombosis in the lumen. The extension hub for each lumen is labeled to provide positive identification of lumen size and location. The body has depth markings, measured in cm from the distal end, that facilitate correct placement of the tip. The device is radiopaque to allow verification of location in the patient. The atraumatic distal tip minimizes patient trauma during insertion.

Scientific concepts that form the basis for the device:

The multi-lumen catheter is made of polyurethane to safely perform the functions described above. Thirty-percent Barium Sulfate is included in the main tube to cause radiopacity. The device has been tested to international standards to demonstrate biocompatibility. The lumens are sized to perform their individual functions.

Intended Use of Device:

The device is used to measure central venous pressure, to infuse fluids, to sample venous blood and to infuse parenteral nutrition (TPN) or medications.

Comparison of Technological Characteristics to legally marketed device:

Both devices have a main (multiple lumen) tube made of polyurethane. The colorants are assumed to be different. Maxxim Medical does not know the colorant used in the legally marketed device. This includes the colorants used in the body, tip and hubs and the ink used for marking. This difference does not affect the safety and effectiveness of the device. The Argon catheter has been completely tested for biocompatibility.

Both devices have clear extension tubes made of polyurethane.

In the legally marketed device the multiple lumen tube and the extension tubes are all insert-molded into the bifurcation hub. In the Maxxim Medical device only the multiple lumen tube is insert molded into the bifurcation hub. The multiple lumen tube is molded deeper into the hub than it is in the legally marketed device. This is an improvement in the device in that the possibility of cross-flow between lumens is significantly reduced. Instead of being insert-molded into the bifurcation hub the extension tubes are solvent-bonded on the Maxxim Medical device. The break forces of the Maxxim Medical extension tubes are much stronger than those of the legally marketed device. Thus for

both reasons, safety and effectiveness of the device is improved over the legally marketed device.

On the legally marketed device the extension tubes have the extension lines identified by printing on the lines themselves. The Maxxim Medical device has the extension line identification printed on the extension hubs instead of on the lines. This is an improvement in safety and effectiveness. If a clear line is full of blood the printing will be harder to read than with a line having the printing on the hub.

Clinical data:

Clinical data are not needed for this device.

CONCLUSIONS:

Maxxim Medical concludes that the Argon Multi-Lumen Central Venous Catheter is substantially equivalent to the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 5 1999

Mr. Eddie Monroe, VP QA/RA
Maxxim Medical
Argon Division
1445 Flat Creek Road
Athens, Texas 75751

Re: K984189
Trade Name: Argon Multi-Lumen Central Venous Catheter
Regulatory Class: II
Product Code: FOZ
Dated: March 31, 1999
Received: April 5, 1999

Dear Mr. Monroe:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K984189

Device Name: Argon Multi-Lumen Central Venous Catheter

Indications for Use:

Multi-lumen central venous catheters are used to measure central venous pressure, to infuse fluids, to sample venous blood and to infuse parenteral nutrition (TPN) or medications.

X Prescription Use

(Division Sign Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984189