DEC 21 1999

**510(k) Number: K990173**

**510(k) SUMMARY**

***Trade Name***: Pathfinder II Angiographic Catheter

***Common Name:*** Angiographic Catheter

***Classification Name:*** Diagnostic intravascular catheter (per CFR 21 Part 870.1200)

***Product Code:*** DQO

***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:*** May 19, 1999

***Legally marketed device to which equivalence is claimed:***

Cordis Corporation, Super Torque Plus™

***Description of Device***

The Pathfinder II Angiographic catheter has a polyurethane body, reinforced with stainless steel braid, containing barium sulfate and a blue colorant. The braiding provides torque-ability. The barium sulfate causes the device to be radio-detectable under a fluoroscope to assist in placing the device in the patient's vasculature.

The proximal end of the body is bonded to a polycarbonate hub. The distal end has a polyurethane stem fused to the braided body. All catheters have the distal tip formed either into a pigtail for infusing fluids or into a special "selective" shape that is formed to facilitate rapid placement of the device in the desired location in the circulatory system by the doctor. All selective curves have a soft, atraumatic polyurethane tip fused to the stem.

The pigtail catheters have their stems either straight or formed into an angle to allow for user preferences. Pigtail angiographic catheters have a pattern of "side holes" near the distal tip to allow increased infusion flow rate.

The catheter is introduced using the Seldinger Technique, Artery Cut-down (Sones method), or the Introducer Technique.

***Intended Use of Device***:

The Maxxim Medical, Inc. angiographic catheters are designed to be used for delivering radiopaque contrast media into the coronary or peripheral vascular systems.

***Comparison of Technological Characteristics to legally marketed device***:

| Feature | Cordis Super Torque Plus™ | Pathfinder II Angiographic Catheter |
|---|---|---|
| Sterile packaging | On card inserted into a pouch made of Mylar® and Tyvek® | On card or plastic tray inserted into a pouch made of Mylar® and Tyvek® |
| Sterilization method | Ethylene Oxide Gas | Ethylene Oxide Gas |
| Shelf life | Three years | Three years |
| Intended use | to deliver radiopaque contrast media to selected sites in the vascular system. | for delivering radiopaque contrast media into the coronary or peripheral vascular systems. |
| Hub with locking female Luer) taper | Yes | Yes |
| Available sizes (French) | 4 through 8 | 5 through 8 |
| Available lengths (cm) | 80 through 125 | 65 through 125 |
| Maximum guide wire O.D. (inches) | .038 | .038 |
| Hub material | Polycarbonate | Polycarbonate |
| Reinforcement braid material | 300 Series stainless steel | 300 Series stainless steel |
| Device radiopaque | Yes | Yes |
| Shaft (body) material | Polyurethane | Polyurethane |
| Stem material | Polyurethane | Polyurethane |
| Atraumatic tip material | Polyurethane | Polyurethane |
| Stem to atraumatic tip attachment method | Heat fuse | Heat fuse |
| Stem to body attachment method | Heat fuse | Heat fuse |
| Maximum pressure (psi) | 1200 | 1200 |
| Strain relief | No | Yes |
| Catheter identification printed on hub | Yes | Yes |

The colorants are assumed to be different. Maxxim Medical does not know the colorant used in the legally marketed device. This includes the braided body, the stem, the hub, the strain relief and the ink used for marking. This difference does not affect the safety and effectiveness of the device.

Both devices have a soft polyurethane tip on selective catheters and side holes on pigtail catheters. The Pathfinder II Angiographic Catheter tips are made of polyurethane, white colorant and barium sulfate. The material of the legally marketed device is presumed to be similar. If there is a difference, it does not affect the safety and effectiveness of the device.

The Maxxim Medical device has been tested for biocompatibility as required by ISO 10993-1.

***Summary Of Non-Clinical Performance Data***

The Pathfinder II Angiographic Catheter has been tested to the following consensus standards:

1. ISO 10555-1:1995(E) Sterile, single use intravascular catheters – Part 1: General Requirements

2. ISO 10555-2:1996(E) Sterile, single use intravascular catheters – Part 2: Angiographic catheters.

3. ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing.

4. ISO 594/1-1986(E) Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements

5. ISO 594-2-1986(E) Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock Fittings

Among the performance data tested and compared were tensile strength of all bonds, flow rates and burst strength.

***Clinical Data:***

Clinical data are not needed for this device.

***Conclusions:***

We conclude that the Pathfinder II Angiographic Catheter is safe and effective and is equal to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1999

Mr. Eddie Monroe
Maxxim Medical
1445 Flat Creek Road
Athens, TX 75751

Re: K990173
Pathfinder II Angiographic Catheter
Regulatory Class: II (two)
Product Code: 74 DQO
Dated: September 21, 1999
Received: September 27, 1999

Dear Mr. Monroe:

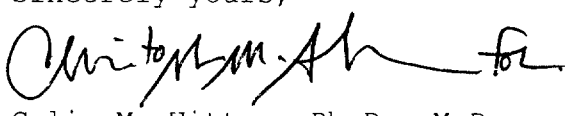
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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"(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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990173

Device Name: Pathfinder II Angiographic Catheter

Indications For Use:

The Maxxim Medical angiographic catheters are designed to be used for delivering radiopaque contrast media into the coronary or peripheral vascular systems

(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)

Christopher M. Hunter for Written

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990173