K024000

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angiometrx

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Summary of Safety and Effectiveness
K024000

Trade Name	**Metricath™ System**
Submitted by:	**Angiometrx Inc.**, a division of Medical Ventures Corp. 1099 8th Avenue West, Unit 107 Vancouver, British Columbia Canada, V6H 1C3 Tel: (604) 742-3810 Fax: (604) 742-3812 Contact Person: Tim Verspagen, RAC
Intended Use	The Metricath™ System is intended for measuring intravascular diameter and cross-sectional area, in the coronary arteries only.
Device Description	The Metricath™ System consists of two parts, the Metricath™ 1000 computer console, and the sterile, disposable Metricath™ Balloon Catheter. The Metricath™ System measures both artery lumen diameter and cross sectional area using a low-pressure balloon catheter inserted into the artery using standard interventional procedures and techniques. The Metricath™ System is indicated for use in patients who are candidates for percutaneous transluminal interventional procedures to make arterial lumen measurements proximal to a lesion, or within a stented section of an artery.
Classification	Classification: Class II Product Code: DQO Classification Name: Diagnostic Intravascular Catheter
Predicate Devices	1. Galaxy Intravascular Ultrasound System (Boston Scientific) 2. UltraCross™ 2.9, 30MHz Coronary Imaging Catheter (Boston Scientific) 3. Equinox™ Occlusion Balloon Catheter (Micro Therapeutics) 4. Amplatzer® Sizing Balloon (AGA Medical)

Functional & Safety Testing	The Metricath™ 1000 Console met or exceeded the requirements of IEC 60601-1 and IEC 60601-1-2 regarding safety of medical electrical equipment. The Metricath™ 1000 Console software has been successfully validated. The Metricath™ Balloon Catheter met or exceeded the requirements of ISO 10555-1 and ISO 10555-4 regarding sterile intravascular (balloon) catheters and ISO 10993 regarding biocompatibility. The following characteristics of the Metricath™ Balloon Catheter were evaluated: tensile strength of catheter bonds; catheter leakage, burst, kinking, tortuosity and fatigue. The Metricath™ System has been tested in-vivo, and found safe and effective for its intended use.
Conclusion	The Metricath™ System has been tested and compared to the predicate devices, and found to be substantially equivalent with regards to device safety and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2003

Angiometrx, Inc.
c/o Mr. Tim Verspagen
Regulatory Affairs Manager
107-1099 8th Avenue West
Vancouver, BC V6H 1C3
Canada

Re: K024000
Trade Name: Metricath System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: May 2, 2003
Received: May 6, 2003

Dear Mr. Verspagen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number: K024000

Device Name: The Metricath System

Indications for Use:

The Metricath System is indicated for use as an adjunct to conventional angiographic procedures to provide measurements of arterial lumen cross sectional area and diameter of the coronary vasculature. Metricath Balloon Catheter is indicated for use in patients who are candidates for percutaneous transluminal interventional procedures to make arterial lumen measurements proximal to a lesion, or within a stented section of an artery.

(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 Cardiovascular Devices

510(k) Number K024000

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