FEB 21 2003

510(k) Summary

Sponsor

Name & Address: CoAxia, Inc.
10900 73rd Avenue N. Suite 102
Maple Grove, MN 55369
Telephone: 763-315-8383
FAX: 763-315-3660

Contact person: Gregory W. Sachs
Vice President - Clinical, Regulatory and Quality Assurance

Date Prepared: November 21, 2002

Name and Classification

Trade Name: CoAxia FloControl™ Catheter
Common Name: Peripheral Vascular Occlusion Balloon
Predicate Device(s): Equinox™ Occlusion Balloon System (K990487)
Heartport® Endoaortic Clamp™ Catheter (K974175)
MedComp® DUO-COAT Catheter Double Lumen (K991320)
SetPoint® Endovascular Temperature Management System (K012512)

Device Description

The CoAxia FloControl™ Catheter is a 9F multi-lumen device with two balloons mounted near the distal tip. The catheter is inserted over a .035" guide wire through a 9F introducer sheath. The device has a working length of 62 cm and is coated with a hydrophilic, heparin coating. A multi-port manifold at the proximal end of the device allows balloon inflation, guide wire insertion and attachment of a pressure monitoring line. Each balloon is 2 cm (20 mm) in length, separated by a distance of 8cm. Each balloon can be inflated independently to a diameter from 10mm to 20mm to control blood flow in the selected vessel. The device has 3 marker bands to aid in balloon placement. The catheter is EtO sterilized and is intended for single use only.

Intended Use

The CoAxia FloControl™ Catheter is intended for use in selectively stopping or controlling blood flow in the peripheral vasculature.

Summary of Studies

The CoAxia FloControl™ Catheter was tested in accordance with ISO, EN and FDA's Guidance for Use of Short-term and Long-term Use Intravascular Catheters. Testing included tensile strength, balloon characterization, dimensional verification, accessory compatibility, trackability, coating integrity, pressure monitoring capability, shelf life and biocompatibility. All testing demonstrated acceptable performance in accordance with the device specifications. Clinical testing of the FloControl catheter was not performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2003

CoAxia, Inc.
c/o Mr. Gregory W. Sachs
Vice President - Clinical, Regulatory and Quality Assurance
10900 73rd Avenue N., Suite 102
Maple Grove, MN 55369

Re: K023914
Trade Name: CoAxia FloControl™ Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Catheter, Intravascular Occluding, Temporary
Regulatory Class: Class II (two)
Product Code: MJN
Dated: November 22, 2002
Received: November 25, 2002

Dear Mr. Sachs:

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

K023914

Indications for Use

510(k) Number: To be assigned

Device Name: CoAxia FloControl™ Catheter

Indications for Use: The CoAxia FloControl™ Catheter is intended for use in selectively stopping or controlling blood flow in the peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023914

ORIGINAL