OCT 2 8 2002

ArteriA™

**510(k) Summary** **K021210**
**ArteriA Occlusion Balloon**

**Date Prepared: August 14, 2002**

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

**Submitter**

ArteriA Medical Science, Inc.
The Presidio, Building 220, Suite 120
San Francisco, CA 94129

**Company Contact**

Alan Hinton, Quality Assurance

**Device Name**

Trade Name: ArteriA Occlusion Balloon

Common Name: Balloon Occlusion Catheter

Classification Name: Catheter, Intravascular Occluding Temporary

**Predicate Devices**

MicroTherapeutics, Inc., Equinox™ Occlusion Balloon Catheter, K990487

MicroTherapeutics, Inc., HyperForm™ Occlusion Balloon Catheter, K011656

**Description of Device**

The ArteriA Occlusion Balloon is a single lumen, intravascular catheter with a compliant balloon at the distal end. An adapter at the proximal end of the shaft accesses the lumen. The catheter is constructed of stainless steel and a composite device designed to access the vessel. The proximal end of the catheter is fitted with an adapter. This adapter connects to the balloon inflation lumen and a fitting for attachment of a standard inflation syringe. The ArteriA Occlusion Catheter is supplied sterile and for single use.

**Intended Use**

The ArteriA Occlusion Balloon Catheter is indicated for use as an intravascular occluding catheter with an inflatable balloon tip that is used for temporary occlusion of vessels. This technique of temporary occlusion is useful in selectively stopping or controlling blood flow. The ArteriA Occlusion Balloon may be used in the peripheral and neuro-vasculature where temporary occlusion is desired during endovascular procedures.

**Tests Submitted**

Biocompatibility of the ArteriA Occlusion Balloon was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the ArteriA Occlusion Balloon when tested as an external communicating, blood contact, short duration (<24 hrs.) device.

The sterilization process was validated to a Sterility Assurance Level (SAL) of $10^{-6}$ in accordance with ISO 11135, Validation and routine control of ethylene oxide sterilization.

Performance testing of the ArteriA Occlusion Balloon was conducted in accordance with ISO 10555, Sterile, single use intravascular catheters, Parts 1 and 4. Tests included dimensional verification, balloon compliance and integrity, catheter tensile strength, torque strength, flexibility and trackability. Test results demonstrate that the device meets or exceeds the requirements of these standards.

**Comparison of Technological Characteristics**

The basic technologies, design and function of ArteriA Medical Science, Inc.'s ArteriA Occlusion Balloon are substantially equivalent in design, materials of construction, function, and intended use to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 8 2002

ArteriA Medical Science, Inc.
c/o Mr. Alan C. Hinton
The Presidio, Building 220 Suite 120
San Francisco, CA 94129

Re: K021210
ArteriA Occlusion Balloon
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II (two)
Product Code: MJN
Dated: August 14, 2002
Received: August 16, 2002

Dear Mr. Hinton:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

510(k) Number :

Device Name : ArteriA Occlusion Balloon

Indications for Use:

The ArteriA Occlusion Balloon is indicated for use as an intravascular occluding catheter with an inflatable balloon tip that is used for temporary occlusion of vessels. The technique of temporary occlusion is useful in selectively stopping or controlling blood flow. The ArteriA Occlusion Balloon may be used in the peripheral and neuro-vasculature where temporary occlusion is desired during endovascular procedures.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter ____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022210