AUG 2 2 2002

K021293

ArteriA

510(k) Summary
ArteriA Blood Filter

Date Prepared: July 31, 2002

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

A. Submitter

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

B. Company Contact

Alan Hinton, Quality Assurance

C. Device Name

Trade Name:	ArteriA Blood Filter
Common Name:	Blood administration filter
Classification Name:	Intravascular Administration Set

D. Predicate Devices

Baxter healthcare Corporation, Blood Administration Set, K993120

E. Description of Device

The ArteriA Blood Filter device is a blood transfusion filter and drip chamber connected to flexible medical grade tubing having a connector on each end. The input side to the drip-chamber/filter has a three-way stopcock valve that has both a male and female Luer connections available for use. The outlet of the drip-chamber/filter has a male Luer connector that facilitates connection to a venous access device such as a catheter or sheath. It may also be connected to another stopcock.

F. Intended Use

The ArteriA Blood Filter is intended for use as an accessory in the administration of blood, blood components or solutions into a patient's vascular system through a venous access device.

G. Comparison of Technological Characteristics
The basic technologies, design and function of ArteriA Medical Science, Inc.'s ArteriA Blood Filter are substantially equivalent in design, materials of construction, function, and intended us to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 2002

Mr. Alan Hinton
Director, Quality Assurance
Arteria Medical Science, Incorporated
22 Hill Street
Newburyport, Massachusetts 01950

Re: K021293
Trade/Device Name: Arteria Blood Filter
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPB and BRZ
Dated: July 31, 2002
Received: August 2, 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) 594-4618. 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,

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

Enclosure

K 021293

510(k) Number :

Device Name :

Indications for Use :

The ArteriA Blood Filter is intended as an accessory for use in the administration of blood, blood components or solutions into a patient's vascular system through a venous access device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K021293