

AUG 14 1998

Non-Confidential Summary of Safety and Effectiveness

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June 23, 1998

ARC Medical, Inc.
322 Patterson Ave.
Scottsdale, GA 30079

Tel - (404) 373-8300

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Official Contact: Harold B. Norris - President
Proprietary or Trade Name: Circuit Guard
Common/Usual Name: Bacteria Filter accessory
Classification Name: Bacterial filter, breathing circuit
Device: Circuit Guard
Predicate Devices: ARC Filter and Filter / HME - K903056A, K903058A, Concord-Portex
- Steri-Cath - K902383.

Device Description:

The Circuit Guard is a thin-wall sleeve which when attached to a Filter or Filter / HME housing, is pulled over the breathing circuit wye and tubing to cover these items to reduce gross contamination of the circuit components. It is viewed to be similar the intended use of a sleeved suction catheter. This is a modification of our ARC Filter and ARC Filter / HME.

Intended Use:

Indicated Use -- To reduce gross contamination on breathing circuit by covering the patient end of the circuit.
Environment of Use -- Hospital, OR, anesthesia, ICU

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Comparison to Predicate Devices:

Attribute	ARC Circuit Guard	ARC Filter / Filter / HME K903056A K903058A	Concord- Portex Steri-Cath K902383
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Use

Intended to reduce gross contamination on a surface	Yes	--	Yes
Used with breathing circuits, ventilator circuits, resuscitators	Yes	Yes	--
Environment of use - Hospital, OR, anesthesia, ICU	Yes	Yes	Yes
Indicated for single use	Yes	Yes	Yes

Design

Placed in the breathing circuit	Yes	Yes	Yes
Incorporates a thin-walled protective sleeve	Yes	--	Yes

Performance Standards / Specifications

None applicable for proposed modification	Yes	--	Yes
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Materials

Sleeve - Polyethylene	Yes	--	Yes
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Differences between Other Legally Marketed Predicate Devices

The proposed modification to the ARC products does not alter their original intended uses. There is no significant differences between the intended device and the predicate devices.

AUG 14 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Mr. Harold B. Norris
ARC Medical, Inc.
322 Patterson Avenue
Scottsdale, GA 30079Re: K982239
Circuit Guard
Regulatory Class: II (two)
Product Code: 73 CAH
Dated: June 23, 1998
Received: June 25, 1998

Dear Mr. Norris:

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.

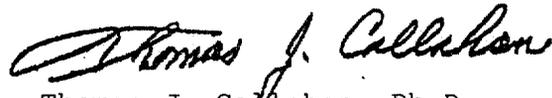
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Harold B. Norris

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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Page 1 of 1

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: K982239 (To be assigned)

Modification to K903056A and K903058A

Device Name: Circuit Guard

Intended Use : To reduce gross contamination on breathing circuits by covering the patient end of a breathing circuit with a protective sleeve.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer
(Division Sign-Off)
Division of **Cardiovascular, Respiratory,**
and **Neurological Devices**
510(k) Number K982239

Prescription Use
(Per CFR 801.109)

or

Over-the-counter use