

JAN 13 2000

K 994208

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY AND CONTACT PERSON

Medtronic Perfusion Systems
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Minneapolis, MN 55428
Tel: 612-391-9000
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Marie Holm, Associate Product Regulations Manager, Regulatory/Clinical Affairs
Debra Kridner, Director of Regulatory/Clinical Affairs

DEVICE NAME

AFFINITY® 20µ Arterial Blood Filter

NAME OF PREDICATED OR LEGALLY MARKETED DEVICE

AFFINITY® 38 µ Arterial Blood Filter (K952532)
INTERSEPT® 20 µ Arterial Blood Filter (K926413)

DESCRIPTION OF DEVICE

The 20 µ arterial blood filter is a single use device designed to filter microemboli from the blood in the extracorporeal circuits during cardiopulmonary bypass surgery.

STATEMENT OF INTENDED USE

The Arterial Filter is indicated for use in cardiopulmonary bypass procedures for the removal of particulate and gaseous microemboli.

STATEMENT OF INTENDED USE OF PREDICATED/MARKETED DEVICE

The Arterial Filter is indicated for use in cardiopulmonary bypass procedures for the removal of particulate and gaseous microemboli.

The INTERSEPT® and Medtronic arterial blood filter is indicated for use in all cardiopulmonary bypass procedures for the removal of particulate and gaseous microemboli from the arterial line.

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

Information regarding technological characteristics comparison is provided in the following section, "Determination of Substantial Equivalence".

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This "**SPECIAL 510(k)**" is being submitted for a modification to the AFFINITY[®] Arterial Blood Filter. The modification is to change only the filter pore size and market both a 38 μ and 20 μ Arterial Blood Filter.

The AFFINITY[®] 20 μ Arterial Blood Filter is being "**compared to the following Marketed Devices**":

- AFFINITY[®] 38 μ Arterial Blood Filter (K952532)
- INTERSEPT[®] 20 μ Arterial Blood Filter (K926413)

The AFFINITY[®] 20 μ Arterial Blood Filter has the "**same indications statement and intended uses**" as the:

- AFFINITY[®] 38 μ Arterial Blood Filter (K952532)
- INTERSEPT[®] 20 μ Arterial Blood Filter (K926413)

The AFFINITY[®] 20 μ Arterial Blood Filter has "**new technological characteristics (e.g., design)**" from the AFFINITY[®] 38 μ Arterial Blood Filter. The new technological characteristic is solely the pore size of the micron filter:

- 20 μ

The technological characteristic of the 20 μ screen is common to other arterial blood filters currently in commercial distribution as follows:

- INTERSEPT[®] 20 μ Arterial Blood Filter (K926413)

This technological characteristic "**could affect the safety and effectiveness of the device**". However, these "**new technological characteristics do not raise new types of safety or effectiveness questions**". In addition, "**there are accepted scientific methods which exist for assessing effects of these new technological characteristics**."

"**Performance data to assess the effects of these new technological characteristics**" has been performed. These "**performance data demonstrate**" that the AFFINITY[®] 20 μ Arterial Blood Filter is substantially equivalent to other marketed arterial filters.

The *in vitro* bench testing demonstrated that when compared to the predicate devices, the AFFINITY® 20 µ Arterial Blood Filter does not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed arterial filters. The *in vitro* bench testing included analysis of:

I. Physical Characteristics

- a. Prime volume
- b. Pressure integrity

II. Performance Characteristics

- a. Pressure drop
- b. Ease of prime
- c. Filtration efficiency
- d. Microemboli removal
- e. Bolus air management
- f. Blood trauma

**JAN 13 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Marie Holm
Associate Product Regulation Manager
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428

Re: K994208
AFFINITY® 20 Micron Arterial Blood Filter
Regulatory Class: III
Product Code: DTM
Dated: December 13, 1999
Received: December 14, 1999

Dear Ms. Holm:

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 (Pre-market 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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

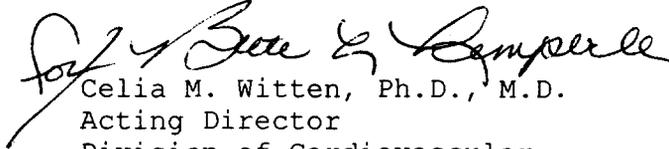
This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

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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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Celia M. Witten".

Celia M. Witten, Ph.D., M.D.

Acting Director

Division of Cardiovascular

Respiratory and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Indications for Use

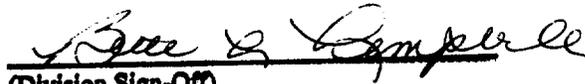
510(k) Number if known: K994208 -

Device Name: AFFINITY® 20 µ Arterial Blood Filter

Indications for Use:

The Arterial Filter is indicated for use in cardiopulmonary bypass procedures for the removal of particulate and gaseous microemboli.

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K994208

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter use _____