K972159

510(k) SUMMARY

JUL 23 1997

Submitted by:

Mary Ellen Snyder
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:
June 6, 1997

Proposed Device:
Modified 40 Micron Transfusion Filter

Predicate Device:
40 Micron Transfusion Filter

Proposed Device Description:

Baxter is currently marketing a 40 Micron Transfusion Filter indicated for the removal of microaggregates from whole blood and red blood cells and for the transfusion of platelets. The filter consists of a fiber pad supported by a single layer screen contained in a housing. The subject of this submission is a change in the fiber composition of the filter pad. Fibers which comprise approximately 50% of the current filter pad are being discontinued by the supplier. These fibers are being replaced with fibers from another supplier which differ in size and material formulation.

Statement of Intended Use:

The proposed 40 micron transfusion filter has the same intended use as the currently marketed 40 micron transfusion filter. The filter is intended for the removal of microaggregates from whole blood and red blood cells and for the transfusion of platelets.

Summary of Technological Characteristics of New Device to Predicate Devices

The design of the proposed 40 micron transfusion filter is identical to the current 40 micron transfusion filter except for a change in the size and material formulation of the fibers which currently comprise about 50% of the filter pad. There are no other changes in the design of the fiber pad or the filter. The materials and design of all other filter components, including the filter housing and filter screen, remain unchanged. The filter is currently ETO sterilized and will now be gamma sterilized.

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Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

The biological and chemical reactivity of the new material has been assessed using biological methods specified in ISO Standard 10993-1 and USP Physicochemical tests. The materials were found to be acceptable for their intended use.

Data regarding the functional performance of the modified 40 Micron Transfusion Filter have been generated. Studies included filter prime time, flow rate, filter capacity, filter integrity (% change in hemolysis), filtration efficiency (% microaggregate removal), residual volume, % white blood cell (wbc) removal, residual wbc count, and % rbc recovery on packed red blood cells. Studies were also performed with platelets and included platelet count, morphology, pH, % pH change % LDH change and C3a/C5a complement activation. Performance testing indicates that the modified device meets or exceeds all functional requirements and support its suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mary Ellen Snyder
Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073

JUL 23 1997

Re: K972159
Trade Name: Fenwal 40 Micron Transfusion Filter
Regulatory Class: II
Product Code: CAK
Dated: June 6, 1997
Received: June 9, 1997

Dear Ms. Snyder:

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 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 requirement, 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.

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) 594-4618. 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" (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/dsmamain.html".

Sincerely yours,

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

Enclosure

K972159

510(k) Number: Not Available

Device Name: 40 Micron Transfusion Filter

Indication for Use:

The 40 Micron Transfusion Filter is indicated for removal of microaggregate particles from whole blood and red blood cells and for transfusion of platelets.

(Division Sign-Off) Rebecca Cocanti
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972159

Prescription Use ✓
(Per 21 CFR 801.109)

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