

SEP 30 1998

510(k) Premarket Notification
Fenwal® 20 Micron Pediatric Transfusion Filter

K982822

510(k) SUMMARY

Submitted by:

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

Date Prepared:

August 10, 1998

Proposed Device:

Modified Fenwal® 20 Micron Pediatric Transfusion Filter

Predicate Device:

Fenwal® 20 Micron Pediatric Transfusion Filter
Fenwal® 20 Micron High Capacity Transfusion Filter

Proposed Device Description:

Baxter's Fenwal® 20 Micron Pediatric Transfusion Filter is a depth-type filter which traps microaggregates composed of degenerating platelets, leukocytes, fibrin strands and other particles which form in blood after storage. The filter consists of a fiber pad supported by a screen contained in a housing. The subject of this submission is a change in the fiber composition of the filter pad. The filter pad is currently comprised of five types of fiber strands. The supplier of one of the fibers has discontinued production. We are proposing to eliminate two of the five fibers used in construction of the filter pad and increase the percentage composition of the remaining three sizes. This change will make the composition of the 20 micron pediatric filter pad identical to the composition of the pad in the Fenwal® 20 Micron High Capacity Transfusion Filter covered by K830057.

Statement of Intended Use:

The proposed Fenwal® 20 Micron Pediatric Transfusion Filter has the same intended use as the current Fenwal® 20 Micron Pediatric Transfusion Filter. The filter is intended for the removal of microaggregates from whole blood and red blood cells.

Summary of Technological Characteristics of New Device Compared to Predicate Devices

The proposed Fenwal® 20 Micron Pediatric Transfusion Filter is identical to the current Fenwal® 20 Micron Pediatric Transfusion Filter except for a change in the composition of the filter pad. The materials and design of all other filter components, including the filter housing and filter screen, remain unchanged. The modified 20 micron pediatric filter pad is also identical in composition to the Fenwal® 20 Micron High Capacity Filter but is physically smaller to fit into the pediatric-sized housing.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

Test data has been generated comparing the performance of the proposed and current 20 micron pediatric transfusion filters using packed red blood cells. Data regarding filter efficiency (% microaggregate removal), filtration integrity (% hemolysis and red blood count) and filter capacity were collected. Performance testing indicates that the modified device meets or exceeds all functional requirements and supports its suitability for use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 1998

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

Re: K982822
Trade Name: Fenwal® 20 Micron Pediatric Transfusion
Filter Model 4C7701
Regulatory Class: II
Product Code: CAK
Dated: August 10, 1998
Received: August 11, 1998

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 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 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 pre-market notification submission does not affect any obligation you might have under sections 531

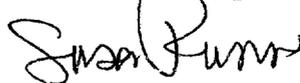
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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 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,



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

Enclosure

510(k) Premarket Notification
Fenwal® 20 Micron Pediatric Transfusion Filter

510(k) Number: Not Available

Device Name: Fenwal® 20 Micron Pediatric Transfusion Filter

Indication for Use:

The Fenwal® 20 Micron Pediatric Transfusion Filter is indicated for the removal of microaggregate particles from whole blood and red blood cells.

Patricia Cuervo

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

510(k) Number 11982822

Prescription Use
(Per 21 CFR 801.109)

AUG 10 1998