K071298

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# HF™ Junior Hemofilter

## 510(k) Summary

AUG - 8 2007


Manufacturer: Minntech Corporation
Address: 14605 28th Ave. N.
Minneapolis, MN 55447

Official Contact: Lynn Lueders
Director, Regulatory Affairs
Minntech Corporation


Device Name:

| | |
|---|---|
| Trade or Proprietary Name: | HF Junior Hemofilter |
| Classification Name: | Per 21 CFR 876.5860 High Permeability Hemodialysis System |
| Common Name: | Hemofilter |

Minntech Corporation has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalency of the HF Junior Hemofilter to other hemofilters currently on the market in the United States.

1. Device Description:

The HF Junior Hemofilter consists of many individual polysulfone hollow fibers encapsulated into a polycarbonate case. The device has arterial and venous ports on opposite ends of the device. As the patient's blood enters the device through the arterial blood port, it passes through the fiber bundle and then exits the device through the venous blood port and is returned to the patient. As the blood passes through the fiber bundle, ultrafiltration occurs as a result of a hydrostatic pressure gradient that exists across the semipermeable membrane. The resulting hemofiltration removes large quantities of plasma water, and small and medium sized solutes (such as IL-6, C3a and C5a) are removed from the vascular space thereby concentrating the red cell mass and the plasma proteins.

2. Intended Use:

The HF Junior Hemoconcentrator is intended for use in prevention or relief of fluid overload, electrolyte and acid imbalances in cases of acute renal failure with oliguria or anuria. Also, it is used to remove excess fluid in cases of congestive heart failure, pulmonary and cerebral edema, anasarca, ascites, septic shock, burns, etc. In hypervolemic patients requiring parenteral nutrition and/or large volume of medications, the hemofilter may be used to reduce fluid overload. In hypercatabolic patients requiring more intensive solute removal, a sterile dialysate fluid may be made to flow around the fibers via the dialysate ports in order to increase the clearance of small molecules. It is indicated for patients (including pediatric patients) according to physician assessment of the patient and the instructions for use.

3. Comparison to Another Device in Commercial Distribution Within the United States

The HF Junior is equivalent in materials and performance to other hemofilters manufactured by Minntech, including the HF Minifilter Plus Hemofilter (K962707) cleared for market in October 1996. The only difference between the HF Junior and the HF Minifilter is that the HF Junior has the same fiber as used in our other HF Hemofilter products. The fiber used in the HF Mini has a larger internal diameter (I.D.) than the fiber that we use for our other HF products (including the HF Junior). Except the I.D., the fiber composition is exactly the same for all of the HF devices.

In addition to the HF Mini, the HF Junior is identical in configuration, size, and materials to the HPH Junior (K050952) cleared in January 2006.

This equivalence has been shown though functional and safety testing as required by the relevant FDA guidances and ISO standards including ISO 8637:2004E, Cardiovascular Implants and Artificial Organs - Haemodialysers, Haemodiafilters, Haemofilters and Haemoconcentrators. This testing, performed on both the HF Junior and the HF Mini for comparison purposes included:

A. determination of the static prime volume,
B. ultrafiltration performance,
C. blood path pressure drop,
D. protein sieving of albumin, myoglobin, and inulin,
E. structural integrity
F. membrane integrity
G. hemolysis
H. aqueous sieving

4. Summary of Substantial Equivalence

Minntech Corporation has provided information to the U.S. FDA to show that the device is safe and effective when used in accordance to its labeling. This information includes evidence that:

a. All materials used in the HF Junior are currently used in Minntech's other HF family of devices. No new materials or manufacturing methods are used to manufacture this device in comparison to the predicate devices.

b. As described in Section 3. above, Minntech has performed extensive testing on the device to show that, the performance characteristics of the HF Junior are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 8 2007

Ms. Lynn Lueders
Director, Regulatory Affairs
Minntech Corporation
14605 28th Avenue North
MINNEAPOLIS MN 55447

Re: K071298
Trade/Device Name: Minntech HF™ Junior Hemofilter
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: May 8, 2007
Received: May 9, 2007

Dear Ms. Lueders:

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 (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 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071298

Device Name: HF™ Junior Hemofilter

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -counter-use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071298