DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2000

Mr. Richard M. Ormsbee
Regulatory Affairs Associate
MINNTECH® Corporation
14605 28th Avenue North
Minneapolis, MN 55447

Re: K000028
Renaflo II HF 2000 Hemofilter
Dated: January 4, 2000
Received: January 5, 2000
Regulatory Class: III
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Ormsbee:

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.

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) 594-4591. 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K000028

Device Name: Renaflo® II HF 2000 Hemofilter

Indications for Use:

The Renaflo® II HF 2000 Hemofilter is intended for use in patients with fluid overload. uremia and/or electrolyte disturbances associated with oligoanuria acute renal failure. It may also be used when removal of excess fluid is indicated, such as patients in pulmonary edema or congestive heart failure refractory to diuretic therapy.

(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)

David A. Segraves
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000028

APR 4 2000

K000028

Page 1 of 2

510(k) SUMMARY

1. Submitter Information:

Name:	Minntech Corporation
Address:	14605 28th Avenue North, Minneapolis, Minnesota 55447
Contact Person:	Richard M. Ormsbee
Date Prepared:	December 20, 1999

2. Device Name:

Proprietary name:	Minntech Renaflo® II HF 2000 Hemofilter
Common name:	Hemofilter
Classification name:	Dialyzer, High Permeability per 21 CFR 876.5860

3. Predicate Device:

Renaflo® II HF 1200 Hemofilter

4. Device Description:

The Minntech Renaflo® II HF 2000 Hemofilter is made of glycerin-free, microporous, hollow fiber, polysulfone membrane encased in a polycarbonate housing having molded ultrafiltration ports and polycarbonate blood port header caps.

5. Indications for Use:

Device	Indications
Minntech Renaflo ® II HF 2000 Hemofilter	The Renaflo ® II HF 2000 Hemofilter is intended for use in-patients with fluid overload, uremia and/or electrolyte disturbances associated with oligoanuria acute renal failure. It may also be use when removal of excess fluid is indicated, such as patients in pulmonary edema or congestive heart failure refractory to diuretic therapy.

6. Technological Characteristics:

A comparative summary of the Renaflo ® II HF 2000 and predicate device is as follows:

Characteristic	Renaflo ® II HF 2000 Hemofilter	Renaflo ® II HF 1200 Hemofilter
Housing	Polycarbonate	Polycarbonate
Potting Material	Polyurethane	Polyurethane
Membrane	Polysulfone	Polysulfone
Membrane Surface Area	1.98 m^2	1.25 m^2
Maximum Transmembrane Pressure (mmHg)	500	500
Blood port connectors	ISO	ISO
Ultrafiltration ports	Luer	Luer
Priming volume (ml)	132	83

7. Performance Testing:

The following performance testing was conducted to determine device effectiveness as a hemofilter: Ultrafiltration Rate vs. Transmembrane Pressure, Pressure Drop vs. Blood Flow Rate, Protein Rejection, Minimum Blood Flow Rate & Blood Path Integrity.