3/8/99

510(k) SUMMARY

1. Submitter Information:

Name:	Fibercor®, Division of Minntech Corporation
Address:	14605 28th Avenue North, Minneapolis, Minnesota 55447
Contact Person:	Mark Murphy
Date Prepared:	September 4, 1998

2. Device Name:

Proprietary name:	FiberFlo™ Hollow Fiber Capsule Water Filters
Common name:	Capsule Filters
Classification name:	Water Purification Subsystem per 21 CFR 876.5665

3. Predicate Device:

FiberFlo™ Hollow Fiber Water Filters

4. Device Description:

The FiberFlo™ Hollow Fiber Capsule Water Filters consist of encapsulated microporous polysulfone membrane in a polycarbonate housing with multiple endcap connections to filter endotoxins, bacteria and particulates from water.

5. Indications for Use:

Device	Indications
Fibercor®FiberFlo™ Hollow Fiber Capsule Water Filters	The FiberFlo™ series of Hollow Fiber Capsule Water Filters is intended to filter bacteria, endotoxin and particulate matter from water used for hemodialysis applications.
Fibercor® FiberFlo™ Hollow Fiber Water Filters	The FiberFlo™ Cartridge series of Hollow Fiber Water Filters is designed to filter bacteria, endotoxin and particulate matter from water used by medical devices.

6. Technological Characteristics:

A comparison of the FiberFlo™ Hollow Fiber Capsule Water Filters and predicate

Characteristic	FiberFlo™ Hollow Fiber Capsule Water Filters	FiberFlo™ Hollow Fiber Water Filters
Case Material	Polycarbonate	Polypropylene
Potting Material	Polyurethane	Polyurethane
Microporous Membrane	Polysulfone	Polysulfone
Membrane Porosity	50, 100 and 200 micron	50, 100 and 200 micron
Sanitizable	Yes	Yes
Water System location	Product water supply lines	Product water supply lines

7. Performance Testing:

The following performance testing was conducted to support substantial equivalence as a water filter for its intended use: Pressure Drop vs. Flow Rate, Endotoxin Rejection, Minimum and Maximum Water Flow Rates and Extractables testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 1999

Mr. Mark Murphy
Regulatory Affairs Associate
MINNTECH® Corporation
14605 28th Avenue North
Minneapolis, MN 55447

Re: K983126
FiberFlo™ Capsule Water Filter
Dated: December 7, 1998
Received: December 8, 1998
Regulatory Class: II
21 CFR 876.5665/Procode: 78 FIP

Dear Mr. Murphy:

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K983126**

Device Name: FiberFlo™ Capsule Water Filter

Indications for Use:

The FiberFlo™ Capsule Water Filter is intended to filter bacteria, endotoxin and particulate matter from water used for hemodialysis applications.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983126 S001