

DEC 11 1998

510(k) SUMMARY**SUBMITTED BY**

Lynn Rodarti
Manager, Regulatory Affairs
INTERPORE Cross International
181 Technology Drive
Irvine, California 92618
(714) 453-3200

Date Submitted: April 3, 1998

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Conventional Hemodialyzer
Common/Usual Name: Ultraconcentrator
Product Classification: Class II
Proprietary Name: UltraConcentrator™ Permeability Hemodialyzer

PREDICATE DEVICE

Quantic Biomedical, Inc. UltraCon™ Ultrafiltrator [reference 510(k) K971710]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

INDICATIONS FOR USE

The UltraConcentrator™ Permeability Hemodialyzer is indicated for use as an ultrafiltrator for the selective removal of undesirable plasma water and small dissolved solutes from blood plasma proteins and formed cellular elements, as may be present in cases of acute hemodilution such as following cardiopulmonary bypass.

DEVICE DESCRIPTION

The UltraConcentrator Permeability Hemodialyzer is a device that is used to remove plasma water from dilute blood plasma proteins, increasing the concentration of plasma proteins and formed cellular elements. The UltraConcentrator is constructed of semi-permeable hollow fibers which divide the device into two compartments. An inner pathway for diluted blood perfusate is defined by the inlet and outlet connectors and flow dispersion

headers which are connected through the inner lumen of semi-permeable, hollow fiber membranes. Surrounding the hollow fibers is an enclosed, vented compartment for the collection of ultrafiltrate waste water.

When perfusate fluid passes through the inner diameter of the hollow fibers, water and small dissolved solutes can pass through the semi-permeable membrane walls into the annular ultrafiltrate compartment to then be discarded.

The UltraConcentrator may be used manually or it may be used with the UltraConcentrator Processor, a pneumatically driven device that provides automatic processing of the UltraConcentrator.

The UltraConcentrator Permeability Hemodialyzer is not intended for use with direct patient connection, nor is it intended for use as a dialyzer. Although constructed of highly permeable membrane material, the low total membrane surface area of the UltraConcentrator inherently limits the maximum rate of water removal. Neither an ultrafiltration rate monitor nor a controller is necessary.+

ULTRACONCENTRATOR SPECIFICATIONS

Overall unit length (cm):	15
Effective fiber length (cm):	11
Unit diameter (cm):	1.8
Membrane area, nominal (m ²)	0.11
Perfusate flow resistance, nominal (mm Hg/mL/min):	0.15
Maximum allowable transmembrane pressure (mm Hg)	500
Priming volume (mL):	5
Residual volume (mL):	1
Hemoconcentration (kUF) typical rate (mL/hr/mm Hg):	1
Molecular weight nominal cutoff (Daltons)	<65,000

CONTRAINDICATIONS, WARNINGS, PRECAUTIONS

While there are no known absolute contraindications to ultrafiltration therapy, maintenance of blood outside the body requires administration of anticoagulants and other medications to the patient or to the collected blood. All drugs and medications should be closely monitored by the prescribing physician to detect any alteration in their effective concentration due to the ultrafiltration process. Because the clearance of some drugs may be variable, the directions and contraindications for use must be in keeping with the patient's medical history and status.

1. Contraindications

The UltraConcentrator is contraindicated for use as a dialyzer or for dialysis with a dialysate. It is also contraindicated for any direct connection to a patient's vascular system or circulating blood volume.

2. Warnings and Precautions

- a. The UltraConcentrator Permeability Hemodialyzer is a device which should only be used by qualified personnel who understand its operation.
- b. This device is intended for single use only. Do not resterilize.
- c. This device was sterilized by gamma irradiation. The blood pathway is sterile and non-pyrogenic in an unopened, undamaged package. Do not use this device if the package is damaged or if perfusate port caps are missing or loose in the package.
- d. Do not exceed a vacuum of 20 inHg (50 cmHg).
- e. Perfusate concentrate to a hematocrit greater than 50% should be avoided.
- f. A minimum perfusate flow rate of 15 ml/min through the UltraConcentrator should be maintained at all times to prevent plugging of membrane channels or clotting.
- g. Blood flow should not exceed 60 ml/min.
- h. The transmembrane pressure must not exceed 500 mmHg. For manual operation, inject the perfusate through the UltraConcentrator over a span of at least 15 seconds.
- i. When used with the Processor, care should be exercised to avoid achieving a hematocrit level greater than 50% in the hemoconcentrate.
- j. Patient blood should at all times be drawn, handled and returned according to applicable established institutional guidelines.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

COMPARISON TO THE PREDICATE DEVICE

The UltraConcentrator is technologically substantially equivalent to the predicate in every respect.

DEC 11 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ms. Lynn Rodarti
Manager, Regulatory Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618-2402Re: K981253/S2
UltraConcentrator Permeability Hemodialyzer
Dated: September 22, 1998
Received: September 23, 1998
Regulatory Class: II
CFR 876.5820/Procode: 78 FJI

Dear Ms. Rodarti:

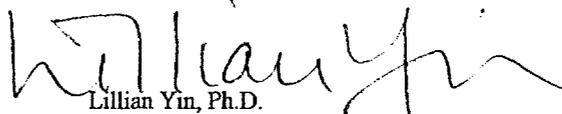
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981253

Device Name: UltraConcentrator™ Permeability Hemodialyzer

Indications for Use:

The UltraConcentrator™ Permeability Hemodialyzer is indicated for use as an ultrafiltrator for the selective removal of undesirable plasma water and small dissolved solutes from blood plasma proteins and formed cellular elements, as may be present in cases of acute hemodilution such as following cardiopulmonary bypass.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(PER 21 CFR 801.109)

OR

Over-The-Counter Use

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K981253/5⁰⁰²