K971710

FEB 27 1998

510(k) SUMMARY

SUBMITTED BY:

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Date Submitted: February 24, 1998

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Conventional Hemodialyzer, under 21 CFR 876.5820

Common or Usual Name: Ultrafiltrator

Proprietary Name: UltraCon™ Ultrafiltrator

PREDICATE DEVICES

Predicate Device 1; Altra FLUX™ 140 Hemodialyzer,
Althin Medical, Inc.
Reference Number K945620/A.

Predicate Device 2; Minifilter™ Hemofilter,
Amicon Division, WR Grace & Co.
Reference Number unknown.

Predicate Device 3; Hemocor HPH™ 400 Hemoconcentrator,
Minntech Corporation.
Reference Number unknown.

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INDICATIONS

The UltraCon™ Ultrafiltrator 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 Ultracon™ Ultrafiltrator is constructed of semipermeable 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 semipermeable hollow fiber membranes. Surrounding the hollow fibers is an enclosed, vented compartment for the collection of ultrafiltrate waste water.

When dilute blood or a blood component is allowed to pass through the perfusate pathway, the device acts as an ultrafilter, removing a percentage of the plasma water and small solutes from the perfusate. When perfusate fluid passes through the inner diameter of the hollow fibers, water and small dissolved solutes can pass through the semipermeable membrane walls into the annular ultrafiltrate compartment, to then be discarded. This results in the concentration of formed elements and proteins as they pass along the perfusate pathway.

The UltraCon™ Ultrafiltrator is built with dry cellulose diacetate membranes, a unique material which has been shown to have a high level of biocompatibility. The absence of any bore fluid provides the convenience of using the device without the need for rinsing. Each device is supplied in a sealed plastic and foil package, to maintain a sterile, non-pyrogenic perfusate pathway.

Although constructed of highly permeable membrane material, the low total membrane surface area of the UltraCon™ Ultrafiltrator inherently limits the maximum rate of water removal. Neither an ultrafiltration rate monitor nor a controller is necessary. Average ultrafiltration rate will vary directly according to perfusate flow rate, transmembrane pressure, or temperature, and inversely according to its protein concentration and hematocrit.

UltraCon™ Ultrafiltrator 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 (TMP), mm Hg	500
Priming volume, ml	5
Residual volume, ml	1
Hemo-concentration (k_{UF}) typical rate, ml/hr/mm Hg	1
Molecular weight nominal cutoff, Daltons	< 65,000

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CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND COMPLICATIONS

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.

The UltraCon™ Ultrafiltrator is contraindicated for use with direct patient connection. Use as a dialyzer, or for any dialysis procedure, is also contraindicated.

The UltraCon™ Ultrafiltrator is intended for use solely by a physician, or under the direction of a physician by qualified personnel who understand its operation, and by prescription only. It is intended for single patient, single procedure use only, and should not be resterilized or reused.

The UltraCon™ Ultrafiltrator is sterilized by gamma irradiation. The blood pathway is sterile and nonpyrogenic in an unopened, undamaged package. The product should not be used if the protective package is damaged or if the perfusate port caps are missing. Aseptic technique is required to avoid contamination of the perfusate pathway when making connections.

During set up and priming, a leak test should be conducted to detect perfusate pathway leaks. During use, the filtrate should be carefully monitored for the appearance of blood, indicating a leak within the device. If red cells appear in the filtrate during use, a fiber rupture has occurred and the leaking device should be replaced with a new device. Perfusate flow rates should not exceed 60 ml/min and transmembrane pressures must not exceed 500 mm Hg. A vacuum regulator should be used if vacuum suction is desired for increased fluid removal rates. Rapid alterations of flow or transmembrane pressure may cause leakage. Perfusate flow and filtrate vacuum settings should be increased or decreased gradually.

The UltraCon™ Ultrafiltrator is made with a highly permeable membrane. Ultrafiltration will occur if the filtrate line is unclamped, even without applied vacuum. If no ultrafiltration is required, the filtrate line should be clamped. The high permeability of this ultrafilter allows high concentration levels to be achieved. Perfusate concentration to a hematocrit greater than 50% should be avoided. A minimum perfusate flow rate of 15 ml/min through the ultrafiltrator should be maintained at all times to prevent plugging of membrane channels or clotting. During use, the filtrate collection chamber must be positioned below the ultrafiltrator to prevent back filtration.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Product design, materials of construction, and function as an ultrafiltrator are substantially equivalent to FDA cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 1998

Quantic Biomedical, Inc.
c/o Glenn N. Byrd, MBA
Associate Director of Regulatory Affairs
Advanced Bioresearch Associates
1700 Rockville Pike, Suite 450
Rockville, MD 20852

Re: K971710
UltraCon™ Ultrafiltrator
Dated: February 24, 1998
Received: February 25, 1998
Regulatory Class: II
21 CFR 876.5820/Procode: 78 FJI

Dear Mr. Byrd:

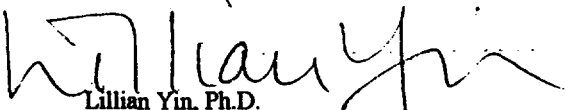
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

3) INDICATIONS FOR USE

510(k) Number: K971710

Device Name: UltraCon™ Ultrafiltrator

Indications for Use: The UltraCon™ Ultrafiltrator is indicated for use as an ultrafiltrator for the selective removal of undesireable 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 cardio-pulmonary bypass.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D Sailing

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971710

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____

Prescription Use, by or on the order of a physician (PER 21 CFR 801.109)