AUG 1 5 2002

K022348

510(k) SUMMARY

SUBMITTED BY

Ms. Prosie Rey-Fessler, RAC
Director, Quality Assurance and Regulatory Affairs
Interpore Cross International
181 Technology Drive
Irvine, California 92618

July 18, 2002

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

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Autotransfusion Apparatus
Common/Usual Name: Sequestration or Separation Device
Product Classification: Class II
Proprietary Name: Access™ System

PREDICATE DEVICE

The main predicate device is the Interpore Cross International Access™ Sequestration System under K012406 dated March 26, 2002. The predicate for the ancillary unit is the Interpore Cross International UltraConcentrator™ System under K011148 dated June 13, 2001.

INDICATIONS-FOR-USE

The Interpore Cross International Access™ System is intended to separate and collect an autologous plasma fraction rich in platelets and white cells from the patient's whole blood perioperative to a surgical procedure.

DEVICE DESCRIPTION

The Interpore Cross International Access™ Concentration System consists of a table-top, autotransfusion apparatus provided with an ancillary filtration unit and a single-use processing disposable set designed to allow separation and collection of an autologous plasma fraction rich in platelets and white cells from the patient's whole blood perioperative to a surgical procedure. The Access™ System is comprised of two major components:

a) **Reusable table-top apparatus**: The Access machine is an electromechanical microprocessor-controlled device contained in an enclosure which incorporates the following system components: the user display and function keys, centrifuge rotor, centrifuge chamber housing, peristaltic pumps, red

blood cell sensors, bubble sensor, pinch valves, vacuum pump and power supply units. The system also includes electronic components and system software which control and monitor the blood processing steps.

b) **Single Use Processing Disposable set**: The Access System Disposable Set consists of a separation chamber, a filter, holding and collection bags, and associated tubing, clamps, connectors and protective caps. Connection of this set to a whole blood reservoir allows the blood processing to be carried out.

COMPARISON TO THE PREDICATE DEVICE

The Access™ System is substantially equivalent to the predicate devices. Based on the same intended use, technological characteristics and comparative performance, Interpore Cross International believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent to its predicate.

SUMMARY OF TESTING

Based on the performance testing conducted, the proposed modified device has been demonstrated to be substantially equivalent to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2002

Interpore Cross International
c/o Ms. Prosie Rey-Fessler, RAC
Director, Quality Assurance and Regulatory Affairs
181 Technology Drive
Irvine, CA 92618-2402

Re: K022348
Trade Name: Access™ System
Regulation Number: 21 CFR 868.5830 and 876.5820
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC and FJI
Dated: July 18, 2002
Received: July 19, 2002

Dear Ms. Rey-Fessler:

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 (PMA), 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Access™ System

Indications for Use:

The Interpore Cross International Access™ System is intended to separate and collect an autologous plasma fraction rich in platelets and white cells from the patient's whole blood perioperative to a surgical procedure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

8/17/02

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K022348