

K983022

APR 2 1999

PART 10
Summary of Safety and
Effectiveness Information

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The contents of this 510(k) summary have been provided in conformance with 21 CFR §807.92.

510(k) Summary for the Harvest Technologies SmartCell Processing System

Submitter's Name and Address: Harvest Technologies Corp.
77 Accord Park Drive, D-7

Phone Number: 781-982-1900

Telefax Number: 781-982-7288

Contact Person: Richard Lariviere, Operations Manager

Date Summary Prepared: August 26, 1998

Device Trade Name: SmartCell Processing System

Common name: Autotransfusion Device

Classification Name: Autotransfusion Apparatus per 21 CFR
868.5830

Substantial Equivalence: The proposed device is substantially equivalent to devices previously cleared by the FDA via the Premarket Notification process for autotransfusion (i.e., Haemonetics Cell Saver 5 Autotransfusion System)

Device Description: The SmartCell System includes the following two components:

Reusable SC-1000, SmartCell hardware system that includes the following major system components: start/stop/clear buttons, process indicator display, process indicator lights, HES and blood pumps, two processing chambers (left and right), fluid sensors, optics and drain controls. The system also includes the electronic components and system software that monitors proper installation of the disposable and the sedimentation process.

The SCP-1500, Process Pack: a sterile, disposable device to transfer and contain the blood and sedimentation fluid (HES) during concentration and transfer to the preconnected filtered reinfusion bag. Also a separate disposable Processing Bag (SCP-1550) is provided that is a sub-assembly of the Process Pack. The SCP-1550 is provided to allow for processing of additional volumes of blood.

Intended Use:

The SmartCell™ Processing System is indicated for the processing of autologous shed blood collected intraoperatively or postoperatively to obtain concentrated red blood cells for reinfusion.

Technological Characteristics:

With the SmartCell device, the concentration of red blood cells is accomplished via a non-mechanical, accelerated gravitational sedimentation process using a commercially available sterile 6% hydroxyethyl starch solution (e.g., Hetastarch). Hydroxyethyl starch (HES) promotes red cell aggregation (rouleaux) thereby accelerating the sedimentation and concentration process. This process yields a packed red cell product with a hematocrit and anticoagulant washout equivalent to that of the predicate device. In vitro blood quality studies, electrical safety testing and biocompatibility evaluation of the disposable set has been performed to demonstrate substantial equivalence.



APR 2 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard Lariviere
Operations Manager
Harvest Technologies, LLC.
77 Accord Park Drive, D-7
Norwell, MA 02061

Re: K983022
SmartCell™ Processing System
Regulatory Class: II (Two)
Product Code: 74 CAC
Dated: January 7, 1999
Received: January 13, 1999

Dear Mr. Lariviere:

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.

Page 2 - Mr. Richard Lariviere

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) 594-4648. 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,


Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

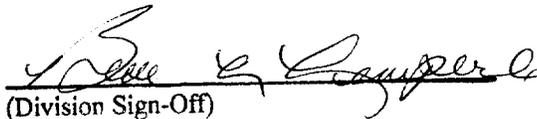
510(k) Number (if known): K983022

Device Name: SmartCell™ Processing System

Indications for Use: The SmartCell™ Processing System is indicated for the processing of autologous shed blood collected intraoperatively or postoperatively to obtain concentrated red blood cells for reinfusion

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K983022

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____