K991430

MAY 28 1999

510(k) Summary for the Harvest Technologies SmartPReP Centrifuge System

Submitter's Name and Address:	Harvest Technologies Corp. 77 Accord Park Drive, D-7
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Contact Person:	Richard Lariviere, Operations Manager
Date Summary Prepared:	April 22, 1999
Device Trade Name:	SmartPReP™ Centrifuge System
Common name:	General Purpose Centrifuge for Clinical Use
Classification Name:	General purpose laboratory equipment labeled or promoted for a specific medical use (21 CFR 862.2050)
Substantial Equivalence:	The proposed device is substantially equivalent to other table-top centrifuges previously cleared by the FDA via the 510(k) Notification process
Device Description:	**SmartPReP Centrifuge System:** Includes a table-top, self-decanting, swinging bucket centrifuge and processing disposable designed to allow for rapid automatic separation of plasma and platelets. The centrifuge spins at a maximum speed of 6000 rpms at a maximum force of approximately 3550g.
Intended Use:	The Harvest SmartPReP Centrifuge System is designed to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood.
Technological Characteristics:	The proposed device has the same technological characteristics and is similar in design and configurations compared with the predicate device (See Table 6-1).

TABLE 6-1
COMPARISON OF THE
HARVEST SMARTPReP AND PREDICATE CENTRIFUGES

Features	**SmartPReP (This Submission)**	**Predicate Centrifuge**
Principle of Operation	Separation based on density of liquids	Separation based on density of liquids
Table-Top	Yes	Yes
Refrigerated	No	No
Swinging Bucket	Yes	Yes
Automatic Decanting	Yes	No
Micro-processor Controlled	Yes	Yes
User Programmable	No, program set by manufacturer	Yes
Speed Control	Preset	Selectable
Acceleration and Braking	Current-controlled	Current-controlled
Maximum RPM	6000 RPM	4000 RPM
Maximum RCF	3550 g	3077 g
Tube Capacity	Two Processing Disposables (50 mL/disposable)	Variety of sizes and volumes up to 250mL
Lid Locking, Lid Holding	Yes	Yes
Imbalance Detector	Yes	Yes
Construction	Anti-torsion construction, metal housing and rotor	Anti-torsion construction, metal housing and rotor

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 28 1999

Richard Lariviere
Operations Manager
HARVEST TECHNOLOGIES CORPORATION
77 Accord Park Drive, D-7
Norwell, MA 02061

Re: K991430
Trade Name: SmartPREP Centrifuge System
Regulatory Class: I
Product Code: JQC
Dated: April 23, 1999
Received: April 26, 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K991430

Device Name: Harvest Technologies SmartPReP™ Centrifuge System

Indications for Use: The Harvest SmartPReP™ CENTRIFUGE SYSTEM is designed to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood.

The plasma and concentrated platelets produced can be used for diagnostic tests.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maleni

(Division Sign-Off)
Division of Clinical Laboratory Devices K991430
510(k) Number

Prescription Use ✓ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109)