DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 13, 2016

Harvest Technologies Corp.
Mr. John D. Bonasera
Director of Regulatory Affairs
40 Grissom Road
Suite 100
Plymouth, MA 02360

Re: K052925
Trade/Device Name: SmartPReP2 Centrifuge System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF, JQC
Dated: October 14, 2005
Received: October 18, 2005

Dear Mr. Bonasera:

This letter corrects our substantially equivalent letter of January 4, 2006.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number if Known: K052925

Device Name: SmartPReP2 Centrifuge System

Indications for Use: The SmartPReP2 Centrifuge System is intended 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 and for preparation of a cell concentrate from bone marrow.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Becker

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K052925

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510(k) Summary for the SmartPReP2 Centrifuge System for Bone Marrow Processing

Submitter's Name and Address:	Harvest Technologies Corp. 40 Grissom Road, Suite 100 Plymouth, MA
Phone Number: **Telefax Number:**	508-732-7530 503-732-0400
Contact Person:	John D. Bonasera, Director, Regulatory Affairs
Date Summary Prepared:	September 20, 2005
Device Trade Name:	SmartPReP2 Centrifuge System
Common Name:	Centrifuge for Clinical Use
Classification Name:	General Purpose Laboratory Centrifuge Labeled or Promoted for a Specific Medical Use Regulation Number: 21 CFR 862.2050
Substantial Equivalence:	The proposed device is substantially equivalent to SmartPReP Centrifuge System described in K991430 and other table-top centrifuges previously cleared by the FDA via the 510(k) Notification process.
Device Description:	The Harvest Technologies SmartPReP2 System includes a table-top, self-decanting swinging bucket centrifuge. The SmartPReP2 Bone Marrow Procedure Pack includes a Process Disposable and other accessories to allow for separation of cells from bone marrow aspirate.
Intended Use:	The SmartPReP2 Centrifuge System is intended 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 and for preparation of a cell concentrate from bone marrow.
Technological Characteristics:	The proposed device has the same technological characteristics and is similar in design and configuration compared with the predicate devices.
Performance Testing:	Results of biocompatibility and performance testing have established that the SmartPReP2 System is suitable for the intended use indicated.