



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 13, 2016

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

Re: K103340

Trade/Device Name: SmartPReP2 Centrifuge System with ACD-A (30ml) and
SmartPReP Centrifuge System with ACD-A (30ml)

Regulation Number: 21 CFR 880.5860

Regulation Name: Piston syringe

Regulatory Class: Class II

Product Code: FMF, JQC

Dated: November 9, 2010

Received: November 15, 2010

Dear Mr. Bonasera:

This letter corrects our substantially equivalent letter of December 6, 2010.

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 FORM

DEC 06 2010

510k Number (if known) K103340

Device Name: SmartPreP®2 Centrifuge System with ACD-A (30ml)

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
Part 21 CFR 801 Subpart D

and

Over-The-Counter Use
21 CFR 810 Subpart C

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Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K103340

INDICATIONS FOR USE FORM

DEC 06 2010

510k Number (if known) K103340

Device Name: SmartPReP™ Centrifuge System with ACD-A (30ml)

Indications for Use: The 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.

Prescription Use
Part 21 CFR 801 Subpart D

and

Over-The-Counter Use _____
21 CFR 810 Subpart C

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


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