K043261

510(k) Summary for the Harvest Graft Delivery System

MAR 11 2005

Submitter's Name and Address:	Harvest Technologies Corp. 40 Grissom Road, Suite 100 Plymouth, MA
Phone Number:	508-732-7530
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Contact Person:	Jack Bonasera, Director, Regulatory Affairs
Date Summary Prepared:	January 24, 2005
Device Trade Name:	Harvest Graft Delivery System
Common Name:	Bone Graft Syringe
Classification Name:	Piston Syringe (Product Code FMF)
Substantial Equivalence:	The Harvest Graft Delivery System is substantially equivalent to other bone graft delivery systems; e.g., Symphony Graft Delivery System marketed by Depuy Acromed (K003286), Wright Medical Technology Bone Graft Syringe (K023088) and INFLITRATE Marrow Infusion Chamber (component of K031817), and the IsoTis OrthoBiologics Aspirex-Bone Marrow Aspirate Kit (K041991).
Device Description:	The Harvest Graft Delivery System consists of a Graft Syringe/Infusion Chamber with pre-seated polymer plug and removable plunger and syringe cap; a dual liquid applicator; female/female luer connector and push rod. A commercially available bone marrow aspirate needle is supplied separately for use with the system.
Intended Use:	The Harvest Graft Delivery System is intended for the aspiration of bone marrow, autologous blood, plasma, or other body fluids. The system is indicated for the delivery of allograft, autograft, or synthetic bone graft materials to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft materials with the aspirate(s), I.V. fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood component(s) as deemed necessary by the clinical use requirements.
Technological Characteristics:	The proposed device has the same technological characteristics and is similar in design and configuration compared with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2005

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

Re: K043261
Trade/Device Name: Harvest Graph Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: March 4, 2005
Received: March 7, 2005

Dear Mr. Bonasera:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number if Known: (K043261)

Device Name: Harvest Graft Delivery System

Indications for Use: The Harvest Graft Delivery System is intended for the aspiration of bone marrow, autologous blood, plasma, or other body fluids. The system is indicated for the delivery of allograft, autograft, or synthetic bone graft materials to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft materials with the aspirate(s), I.V. fluids, blood, plasma, platelet rich plasma, bone marrow or other specific blood component(s) as deemed necessary by the clinical use requirements.

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043261