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510(k) Summary for the Harvest Technologies SmartJet Liquid Grafting Applicator

Applicant's Name and Address:	Harvest Technologies Corp. 40 Grissom Road, Suite 100 Plymouth, MA 02360
Phone Number:	508-732-7500
Telefax Number:	508-732-0400
Contact Person:	John D. Bonasera Director of Regulatory and Quality Affairs
Date Summary Prepared:	March 11, 2002
Device Trade Name:	Harvest SmartJet Grafting Liquid Applicator
Common name:	Applicator, Liquid
Classification name:	Manual Surgical Instrument (21 CFR 878.4800)
Substantial Equivalence:	The device has been cleared by the FDA via the 510(k) Notification process. The purpose of this submission was to describe an expanded indications for use statement.
Predicate Device:	The SmartJet Grafting Liquid Applicator is substantially equivalent to the Harvest SmartJet Bone Grafting Liquid Applicator cleared by FDA in 510(k)011032
Device Description:	The Harvest SmartJet Grafting Liquid Applicator is provided sterile in a sealed pouch and is intended for a single use. The device consists of the following components: Two commercially available disposable medical piston syringes. Applicator Tip (spray or dual cannula) Handle Frame, and Plunger Clip
Intended Use:	The SmartJet Grafting Liquid Applicator is intended for the application of fluids, as deemed necessary by the surgeon's determination of the clinical use requirements, to facilitate the preparation of soft tissue autograft or allograft material prior to the application of the graft material to a repair site.

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Technological Characteristics/ Performance Data	The proposed device has the same technological characteristics and is identical in design and configuration compared with the predicate device. The materials of manufacture have been demonstrated to be suitable for the intended use specified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

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Re: K020252
Trade Name: Smartjet Grafting Liquid Applicator, Models SK/S and LK/2
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: January 20, 2002
Received: January 24, 2002

Dear Mr. Bonasera:

We have reviewed your Section 510(k) premarket 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 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 6382041 or (301) 4436597 or at its Internet address HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.
f/t:410:YPak:mep:3/12/02

INDICATIONS FOR USE STATEMENT

510(k) Number: K020252

Device Name: SmartJet Grafting Liquid Applicator

Indications for Use: The SmartJet Grafting Liquid Applicator is intended for the application of fluids, as deemed necessary by the surgeon's determination of the clinical use requirements, to facilitate the preparation of soft tissue autograft or allograft material prior to the application of the graft material to a repair site.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020252