K023088

OCT 02 2002

WRIGHT MEDICAL TECHNOLOGY

A Wright Medical Group Company

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the Bone Graft Syringe.

Submitted By:	Wright Medical Technology, Inc.
Date:	May 15, 2002
Contact Person:	Roger D. Brown Sr. Director, Clinical and Regulatory Affairs
Proprietary Name:	Bone Graft Syringe
Common Name:	Piston Syringe
Classification Name and Reference:	21 CFR 880.5860 Piston Syringe – Class II
Device Product Code and Panel:	FMF/General Hospital-80

DEVICE INFORMATION

A. INTENDED USE

The Bone Graft Syringe is intended for use as a piston syringe for aspiration of bone marrow, autologous blood, plasma, or other body fluids. The syringe can be used to mix bone graft materials with aspirated fluids and deliver the composite graft material to the orthopedic surgical site.

B. DEVICE DESCRIPTION

The syringe consists of a calibrated hollow barrel and a movable plunger. At the distal end of the syringe there is a male connector nozzle for fitting the female connector (hub) of a single lumen needle. The syringe can be used for withdrawing body fluids and re-injecting the fluids and/or composite graft materials into the body.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, materials, and design features of the Bone Graft Syringe are substantially equivalent to the predicate devices previously cleared for market. The safety and effectiveness of the Bone Graft Syringe are adequately supported by the substantial equivalence information provided within the Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2002

Wright Medical Technology, Inc.
c/o Mr. Mark Job
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K023088
Trade/Device Name: Bone Graft Syringe
Regulation Number: 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: September 13, 2002
Received: September 17, 2002

Dear Mr. Job:

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 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) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

K023088

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BONE GRAFT SYRINGE

INDICATIONS STATEMENT

The Bone Graft Syringe is intended for use as a piston syringe for aspiration of bone marrow, autologous blood, plasma, or other body fluids. The syringe can be used to mix bone graft materials with aspirated fluids and deliver the composite graft material to the orthopedic surgical site.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

Prescription Use ✓
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

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

510(k) Number K023088

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