WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

K971978

JUN 18 1997

510(k) Summary

Contact Person: Cristie Manuel
Date Prepared: May 28, 1997

Trade/Proprietary Name:	Graft Harvesting Sawblade
Common Name:	Surgical instrument motors and accessories/attachments
Product Classification:	Class I
Predicate Devices:	Stryker Sawblade

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Description/Intended Use

The Graft Harvesting Sawblade is a circular, two-piece, oscillating harvesting sawblade used to create a precision circular bone plug 9-11 mm in diameter by 20-30 mm in length. The sawblades will be supplied either sterile for single use, or nonsterile and resterilizable. The Graft Harvesting Sawblade is used with power equipment available from other manufacturers, and is certified by the supplier to work with the power source.

The Graft Harvesting Sawblades are indicated for use as a power accessory in surgical procedures where it is necessary to cut a circular bone plug.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1997

Ms. Cristie Manuel
Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K971978
Trade Name: Graft Harvesting Sawblades
Regulatory Class: I
Product Code: GFA
Dated: May 28, 1997
Received: May 29, 1997

Dear Ms. Manuel:

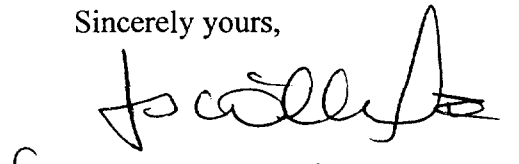
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

C. **Indications for Use of the Device**

510(k) Number (if known):_____

Device Name: Graft Harvesting Sawblades

Indications for Use:

The Graft Harvesting Sawblades are indicated for use as a power accessory in surgical procedures where it is necessary to cut a circular bone plug.

(Please do not write below this line—continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971578

Prescription Use_X_ **Or** **Over-the-Counter Use_____**
(Per 21 CFR 801.109)

(Optional Format 1-2-96)