K022629

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NOV 5 2002

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

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 **WMT- TCP Bone Graft Substitute**.

Submitted By:	Wright Medical Technology, Inc.
Date:	August 6, 2002
Contact Person:	Ehab M. Esmail Manager, Regulatory Affairs
Proprietary Name:	WMT- TCP Bone Graft Substitute
Common Name:	Bone Graft Substitute
Classification Name and Reference:	Filler, Calcium Sulfate Preformed Pellets, Unclassified.
Device Product Code and Panel Code:	Orthopedics/87/ MQV

DEVICE INFORMATION

A. INTENDED USE

WMT- TCP Bone Graft is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. The WMT-TCP is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. WMT- TCP Bone Graft Substitute can be combined with autogenous bone marrow aspirate and/or blood. The product resorbs and is replaced with bone during the healing process.

The WMT- TCP Bone Graft Substitute is provided sterile for single use only and should not be resterilized.

B. DEVICE DESCRIPTION

Apatight-TCP Bone Graft Substitute is a porous calcium phosphate resorbable bone graft substitute for the repair of bony defects. Apatight is an osteoconductive implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. Apatight-TCP Bone Graft Substitute guides the three-dimensional regeneration of bone in the defect site. When placed in direct contact with viable host bone, new bone grows in apposition to the calcium phosphate surfaces of the implant, filling the pores with new bone. As Apatight-TCP Bone Graft Substitute resorbs, bone grows into the space it previously occupied.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material composition, and design features of the WMT- TCP Bone Graft Substitute are substantially equivalent to the intended use, material composition, and design features of the previously submitted APATIGHT™- TCP Bone Graft Substitute (K013966).

The safety and effectiveness of the WMT- TCP Bone Graft Substitute with the expanded indication is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 5 2002

Mr. Ehab M. Esmail
Manager, Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K022629
Trade/Device Name: WMT-TCP Bone Graft Substitute
Regulatory Class: Unclassified
Product Code: MQV
Dated: August 6, 2002
Received: August 7, 2002

Dear Mr. Esmail:

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 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). 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 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,

Miriam C Provost

for 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

WRIGHT MEDICAL TECHNOLOGY

A Wright Medical Group Company

WMT-TCP Bone Graft Substitute

INDICATIONS STATEMENT

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Miriam C. Provost

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

510(k) Number K022629