K072597

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

OCT 15 2007

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 PRO-DENSE™ Core Decompression Procedure Kit.

Submitted By:	Wright Medical Technology, Inc.
Date:	June 21, 2007
Contact Person:	Ryan M. Belaney Regulatory Affairs Specialist II
Proprietary Name:	**PRO-DENSE™** Core Decompression Procedure Kit
Common Name:	Bone Void Filler
Classification Name and Reference:	21 CFR 888.3045 – Resorbable Calcium Salt Bone Void Filler Device – Class II
Device Product Code and Panel Code:	Orthopedic/87/MQV

DEVICE INFORMATION

A. INTENDED USE

The PRO-DENSE™ Core Decompression Procedure Kit, consisting of a bone void filler and manual surgical instruments, is intended to be used during core decompression procedures. The bone void filler component resorbs and is replaced with bone during the healing process. The bone void filler included in the PRO-DENSE™ Core Decompression Procedure Kit is not intended to be used as a load-bearing device.

B. DEVICE DESCRIPTION

The design features of the PRO-DENSE™ Core Decompression Procedure Kit are substantially equivalent to the design features of the PRO-DENSE Bone Void Filler submission (510(k): K070437). The implant material of the PRO-DENSE™ Core Decompression Procedure Kit is exactly the same as the predicate above. The PRO-DENSE Core Decompression Procedure Kit includes Class I and Class II (premarket notification exempt) instrumentation to facilitate a standard core decompression procedure. A brief description of the PRO-DENSE™ implant is provided below.

IMPLANT DESCRIPTION

PRO-DENSE™ consists of a calcium sulfate – calcium phosphate composite bone void filler consisting of a powder component and an aqueous mixing solution. When the two components are mixed, according to directions, an injectable paste is formed which subsequently hardens via hydration reactions. The paste can be injected and cured *in situ* or formed into pellets which can be gently packed into bony defects.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, type of interface, operating principles, shelf life, and design features of the PRO-DENSE™ Core Decompression Procedure Kit are substantially equivalent to the previously cleared PRO-DENSE™ Bone Void Filler 510(k): K070437. Additionally, the safety and effectiveness of the PRO-DENSE™ Core Decompression Procedure Kit is adequately supported by the substantial equivalent 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

Wright Medical Technology, Inc.
Mr. Ryan M. Belaney
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

OCT 15 2007

Re: K072597
Trade/Device Name: PRO-DENSE™ Core Decompression Procedure Kit
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 27, 2007
Received: September 14, 2007

Dear Mr. Belaney:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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: K072597

Device Name: PRO-DENSE™ Core Decompression Procedure Kit

Indications For Use:

The PRO-DENSE™ Core Decompression Procedure Kit, consisting of a bone void filler and manual surgical instruments, is intended to be used during core decompression procedures. The bone void filler component resorbs and is replaced with bone during the healing process. The bone void filler included in the PRO-DENSE™ Core Decompression Procedure Kit is not intended to be used as a load-bearing device.

Prescription Use √ (Per21 CFR 801.109) OR Over-The Counter Use ____ (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucheit for MKM

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

510(k) Number K072597