

K132656

510(K) SUMMARY

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 CFR 807.92(c), this information serves as a Summary of Safety and Effectiveness for the use of the PRODENSE® Bone Graft Substitute.

- 1. Submitted By:** Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002
- Date:** August 23, 2013
- Contact Person:** Leslie Fitch, PhD
Regulatory Affairs Specialist II
Phone: (901) 867-4120
Fax: (901) 867 4190
- 2. Proprietary Name:** PRO-DENSE® Bone Graft Substitute
- Common Name:** Bone Void Filler
- Classification Name and Reference:** 21 CFR 888.3045 – Class II
- Device Product Code, Device Panel:** MQV: Orthopedic
- 3. Predicate Devices:** K113871 – PRODENSE® Bone Graft Substitute
K072597 – PRODENSE® Core Decompression Procedure Kit
- 4. Device Description**

PRODENSE® is indicated as a bone graft substitute to be injected and/or digitally packed into open bone voids/gaps that are not intrinsic to the structural stability of the skeletal system and cure *in-situ*. It is supplied in separate powder and liquid vials along with the instruments for mixing it into a paste and delivering it to the defect site. The triphasic resorption of PRODENSE® results in a scaffold that is osteoconductive allowing tissue infiltration and must eventually be degraded through osteoclastic action as bone remodels within the scaffold. The clinical use of calcium sulfate, calcium phosphate, and composites thereof as a bone void filler has been well established through many peer reviewed publications.

5. Materials

PRO-DENSE® is a calcium sulfate – calcium phosphate composite bone graft substitute consisting of a powder component and an aqueous mixing solution. When the two components are mixed according to directions, an injectable paste forms and subsequently hardens via hydration reactions. The benefits of this composite include:

- Calcium Sulfate
 - Primary osteoconductive filler
 - Resorbs first primarily through simple dissolution to allow early vascular infiltration
 - Excellent clinical history
- Calcium Phosphate
 - Osteoclastic resorption
 - Secondary porous scaffold that is resorbed after primary filler
 - TCP granules are resorbed in the third and final phase

6. Intended Use

PRO-DENSE® resultant paste is intended for use as a bone graft substitute to be injected or digitally packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities and pelvis) to cure *in situ*. These open bone voids may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

The PRO-DENSE® paste cured *in situ* provides an open void/gap filler that can augment provisional hardware (e.g. K Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

PRO-DENSE® is provided sterile for single use only.

PRO-DENSE® Core Decompression Procedure Kit

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.

7. Technological Characteristics Comparison

The components of PRO-DENSE® were slightly adjusted to decrease its set-time. The characteristics of this PRO-DENSE® modification were analyzed according to design control testing and found to be equivalent to the original product. The indications for use of the subject device were not changed as a result of the modification and the fundamental scientific technology of the device, including the bone void filler's mechanism of action, remain identical to the original product.

8. Substantial Equivalence – Non-Clinical Evidence

Design control testing was conducted in accordance with the FDA special control guidance for resorbable calcium salt bone void filler devices. The results of this analysis determined that set-time was the only significantly altered characteristic of the PRODENSE® modification relative to the original product and a risk analysis indicated all risks associated with the PRODENSE® product line remain adequately mitigated.

9. Substantial Equivalence – Clinical Evidence

N/A

10. Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 24, 2014

Wright Medical Technology, Incorporated
Leslie Fitch, Ph.D.
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Re: K132656

Trade/Device Name: PRO-DENSE[®] Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: February 7, 2014
Received: February 20, 2014

Dear Dr. Fitch:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**INDICATIONS FOR USE
STATEMENT**

510(k) Number: K132656

Device Name: PRO-DENSE® Bone Graft Substitute

Indications For Use:

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PRO-DENSE® is provided sterile for single use only.

For the PRO-DENSE® Core Decompression Procedure Kit:

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 ✓
(Per 21 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)

Laurence D. Coyne -5

(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K132656