September 12, 2018

Wright Medical Technology, Inc.
Rachel Roberts
Regulatory Affairs Specialist II
1023 Cherry Road
Memphis, Tennessee 38117

Re: K181255
Trade/Device Name: PRODENSE™ 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, FMF
Dated: July 30, 2018
Received: August 1, 2018

Dear Ms. Roberts:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181255

Device Name
PRODENSE™ Bone Graft Substitute

Indications for Use *(Describe)*

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.

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.

For the Mixing and Delivery System:
The Mixing and Delivery syringe is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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, this information serves as a Summary of Safety and Effectiveness for the use of the PRODENSE™ 2.0 Bone Graft Substitute.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	May 10, 2018
Contact Person:	Rachel Roberts Regulatory Affairs Specialist Office - (901) 867-9708 Fax - (901) 867-4190
(a)(2). Proprietary Name:	PRODENSE™ Bone Graft Substitute
Common Name:	Bone Void Filler, Piston Syringe
Classification Name and Reference:	21 CFR 888.3045 – Class II 21 CFR 880.5860 – Class II
Device Product Code, Device Panel:	MQV, Orthopedic FMF, General and Plastic Surgery
(a)(3). Predicate Device:	K113871 – PRODENSE™ Bone Graft Substitute K072597 – PRODENSE™ Core Decompression Procedure Kit K161568 – Bone Solutions Mixing and Delivery System

(a)(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.

(a)(5). 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.

<u>PRODENSE Core Decompression Procedure Kit</u>

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.

<u>For the Mixing and Delivery system:</u>

The Mixing and Delivery syringe is intended to be used for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

(a)(6). Technological Characteristics Comparison

The subject implant is identical to that of the predicate. The subject includes an updated mixing and delivery system for the implant material as well as new size configurations for the kits. The subject accessories include two sizes of syringe mixers (14 mL and 40 mL); a spindle drive for mechanical assist, a larger delivery syringe, and associated cannulas and adaptors. The update also includes a 40 cc kit with a bowl mixing system.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Dissolution, vicat set time, and diametral tensile strength (DTS) testing showed that the new syringe mixing and delivery systems produced a resultant graft that met all the material specification of the current PRODENSE graft. Biocompatibility and pyrogenicity testing was also performed. The subject 14 mL and 40 mL syringe mixing and delivery systems are acceptable methods for the preparation of the PRODENSE injectable bone graft.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). 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 devices.