



October 21, 2020

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

Re: K200507

Trade/Device Name: PRO-DENSE™ LoVisc 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 26, 2020
Received: March 2, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K200507

Device Name

PRO-DENSE™ LoVisc Bone Graft Substitute

Indications for Use (Describe)

PRO-DENSE™ LoVisc Bone Graft Substitute 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. PRO-DENSE™ LoVisc Bone Graft Substitute resorbs and is replaced with bone during the healing process.

PRO-DENSE™ LoVisc Bone Graft Substitute 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™ LoVisc Bone Graft Substitute is provided sterile for single use only.

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 PRO-DENSE Bone Graft Substitute.

(a)(1) MANUFACTURER IDENTIFICATION

Submitted By: Wright Medical Technology, Inc.
 1023 Cherry Road
 Memphis, TN 38117

Date: October 15, 2020

Contact Person: Rachel Roberts
 Sr Regulatory Affairs Specialist
 Office: (901)867-9708
 Fax: (901)867-4190

(a)(2) SUBJECT DEVICE INFORMATION

Proprietary Name: PRO-DENSE™ LoVisc Bone Graft Substitute
Common Name: Bone Void Filler
Classification Name & Reference: 21 CFR 888.3045 – Class II
Device Product Code & Panel: MQV – Orthopedic

(a)(3) PREDICATE DEVICE INFORMATION

PRO-DENSE Bone Graft Substitute	K181255/K182823
PROSTIM Injectable Inductive Graft	K190283

(a)(4) DEVICE DESCRIPTION

PRO-DENSE™ LoVisc Bone Graft Substitute is a composite of calcium sulfate and calcium phosphate. The formulation consists of a powder component and aqueous mixing solutions. When the two component types are mixed according to directions, an injectable paste is formed. This paste is subsequently injected and/or digitally packed into a bone void where the graft cures and hardens via hydration reactions.

(a)(5) INTENDED USE

PRO-DENSE™ LoVisc Bone Graft Substitute 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 cured paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

The PRO-DENSE™ LoVisc Bone Graft Substitute 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™ LoVisc Bone Graft Substitute is provided sterile for single use only.

(a)(6) TECHNOLOGICAL CHARACTERISTICS COMPARISON

PRO-DENSE™ LoVisc Bone Graft Substitute was developed to provide surgeons with the option of a less viscous version of the predicate PRO-DENSE bone graft substitute. The additional liquid in the implant creates a bone graft material that can be more easily injected into bone voids. The testing showed the set implant to be equivalent to the predicate. The characteristics of the subject device are within the range of the predicate characteristics apart from set time and injectability. The indications for use and the fundamental technology of the subject remain identical to the predicate. The accessories included in the kit are composed of the identical accessories included in the predicate kit.

(b)(1) SUBSTANTIAL EQUIVALENCE – NON-CLINICAL EVIDENCE

Bench top testing was used to characterize and evaluate the chemical, physical, and mechanical properties of the implant. Testing included Fourier Transform Infrared Spectroscopy, X-ray Diffraction Analysis, Dissolution, Porosity, Density, Maximum Exothermic Temperature, Dilute Slurry pH, Vicat and Gilmore Set Time, Injectability, DTS, hardware interaction, sterilization, biocompatibility, pyrogenicity and LAL testing. The characterization testing showed that the subject material is chemically equivalent to the predicate and the bench top testing showed the graft performs within the range of the predicates.

(b)(2) SUBSTANTIAL EQUIVALENCE – CLINICAL EVIDENCE

N/A

(b)(3) SUBSTANTIAL EQUIVALENCE – CONCLUSIONS

The design characteristics of the subject device do not raise any new types of questions of safety or effectiveness. The subject device can be expected to perform at least as well as the predicate systems and are substantially equivalent.