January 5, 2022

Wright Medical Technology, Inc.
Leslie Fitch
Senior Manager, Regulatory Affairs
1023 Cherry Road
Memphis, Tennessee 38117

Re: K213342
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: October 4, 2021
Received: October 7, 2021

Dear Leslie 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. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213342

Device Name
PRO-DENSE LoVisc™ Bone Graft Substitute

Indications for Use *(Describe)*
PRO-DENSE LoVisc™ resultant pastel 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 LoVisc™ 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™ 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

K213342

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 LoVisc™ Bone Graft Substitute.

MANUFACTURER IDENTIFICATION

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

Date: October 4, 2021

Contact Person: Leslie Fitch
Senior Manager, Regulatory Affairs
Office: (901)867-4120
Fax: (901)867-4190

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

PREDICATE DEVICE INFORMATION

Primary : PRO-DENSE LoVisc™ Bone Graft Substitute	K200507
Reference: PRO-DENSE™ Bone Graft Substitute	K181255

DEVICE DESCRIPTON

PRO-DENSE LoVisc™ Bone Graft Substitute is a calcium sulfate formulation consisting 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.

INTENDED USE

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

TECHNOLOGICAL CHARACTERISTICS COMPARISON

PRO-DENSE LoVisc™ minor modifications in this 510k include increased working time, adjusted vial fill volumes, addition of a 20cc size offering, and changes to the size of delivery needles in the kits. The implant material remains the same. The indications for use and the fundamental technology of the subject remain identical to the predicate.

SUBSTANTIAL EQUIVALENCE – NON-CLINICAL EVIDENCE

Ejection testing and LAL testing demonstrated that subject with increased working time, adjusted fill volumes, and updated kit accessories are equivalent to the predicate.

SUBSTANTIAL EQUIVALENCE – CLINICAL EVIDENCE

N/A

SUBSTANTIAL EQUIVALENCE – CONCLUSIONS

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