



May 28, 2019

Wright Medical Technology, Inc.
Alayne Melancon
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K190482

Trade/Device Name: IGNITE™ Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: February 22, 2019
Received: February 27, 2019

Dear Alayne Melancon:

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, Ph.D.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative 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 AdministrationForm Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.**Indications for Use**

510(k) Number (if known)

K190482

Device Name

IGNITE™ Bone Void Filler

Indications for Use (Describe)

IGNITE™ Bone Graft products are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. IGNITE™ Bone Graft products are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

The bone graft syringe is intended for use as a piston syringe for aspiration of bone marrow, autologous blood, plasma, or other body fluids. The syringe can be used to mix bone graft materials with aspirated fluids and deliver the composite graft material to the 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.**

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 IGNITE™ Bone Void Filler.

(a)(1) MANUFACTURER IDENTIFICATION

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

Date: February 25, 2019

Contact Person: Alayne Melancon
Regulatory Affairs Specialist II
Office: (901)290-5986
Fax: (901)867-4190

(a)(2) SUBJECT DEVICE INFORMATION

Proprietary Name: IGNITE™ Bone Void Filler
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

IGNITE™ Bone Void Filler

K052913

(a)(4) DEVICE DESCRIPTION

The IGNITE™ powder is a combination of Human Demineralized Bone Matrix (DBM) with a binding medium of calcium sulfate and carboxymethylcellulose. The IGNITE™ powder is intended to be mixed with bone marrow aspirate (BMA) to form an injectable paste for implantation.

(a)(5) INTENDED USE

IGNITE™ Bone Graft products are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. IGNITE™ Bone Graft products are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

The bone graft syringe is intended for use as a piston syringe for aspiration of bone marrow, autologous blood, plasma, or other body fluids. The syringe can be used to mix bone graft materials with aspirated fluids and deliver the composite graft material to the orthopedic surgical site.

(a)(6) TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject implant material is identical to the predicate. The subject device includes new size offerings and modified accessories for the mixing and delivery of the graft material. The updated system is a syringe mix method for closed mixing.

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

A mixing equivalency evaluation of the subject system was performed in bench top testing. Pyrogenicity testing was also performed. The subject syringe mixing and delivery systems are acceptable methods for the preparation of the IGNITE™ Bone Void Filler.

(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 questions of safety or effectiveness. The subject devices can be expected to perform at least as well as the predicate system and are substantially equivalent.