July 12, 2023

Graftys
Cedric Bonneau
Regulatory Affairs Director
415 Rue Claude Nicolas Ledoux
Eiffel Park Bat. D
Aix en Provence, 13854
France

Re: K231714
Trade/Device Name: GRAFTYS® QUICKSET
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: June 12, 2023
Received: June 12, 2023

Dear Cedric Bonneau:

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,

Jesse Muir -S

Jesse Muir, 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)*
K231714

Device Name
GRAFTYS® QUICKSET

Indications for Use *(Describe)*
GRAFTYS® QUICKSET is intended for bony voids or defects that are not intrinsic to the stability of the bony structure. GRAFTYS® QUICKSET is intended to be placed or injected 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 product provides bone void filler that resorbs and is replaced with bone during the healing process.

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

GRAFTYS® QUICKSET

Submitter Information

GRAFTYS
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Phone: + 33 (0) 4 42 60 30 00

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Contact Person: Cédric Bonneau

Date Prepared: July 12, 2023

Proprietary Name: GRAFTYS® QUICKSET

Common or Usual Name: Filler, bone void, calcium compound

Classification Name : Resorbable calcium salt bone void filler device

Predicate Device:
Primary Predicate Device: K093343, GRAFTYS® QUICKSET; GRAFTYS
Reference Device: K082498, GRAFTYS® HBS; GRAFTYS
Reference Device: K070437, PRO-DENSE™; WRIGHT MEDICAL TECHNOLOGY, INC.

Purpose of the Special 510(k) notice: The GRAFTYS® QUICKSET is a modification of specifications to the cleared GRAFTYS® QUICKSET.

Intended Use/Indications for Use

GRAFTYS® QUICKSET is intended for bony voids or defects that are not intrinsic to the stability of the bony structure. GRAFTYS® QUICKSET is intended to be placed or injected 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 product provides bone void filler that resorbs and is replaced with bone during the healing process.

Device Description

GRAFTYS® QUICKSET is an injectable self-hardening macroporous synthetic calcium phosphate bone substitute. It comes in a double-compartment missing syringe which is pre-filled with a powder (calcium phosphate salts and HPMC) and with a phosphate-based (Na2HPO4) aqueous solution. When these two components are mixed in the syringe, an injectable calcium-deficient apatite is athermally formed. *In vivo*, this apatite, which hardens, is then resorbed and replaced by bone. The injection is administered manually or using a delivery gun. GRAFTYS® QUICKSET is a sterile, non-pyrogenic, single-use product.

Technological Characteristics

The subject device is identical to that of the predicate in terms of chemical composition, intended use/indications for use and operating principles. The subject device has an updated setting time and shelf life.

Performance Data

The proposed device and predicate device have identical chemical composition, physical structure, packaging, packaging, sterilization and manufacturing process. As such, no additional bench testing was conducted. All previous verification and validation testing performed for the predicate device according to the Guidance Class II Special Controls Guidance Document: Resorbable calcium salt bone void filler device; Guidance for Industry and FDA June 2, 2003, cleared under K093343, is still applicable to the modified device excepting for setting time, compressive strength and product shelf life and support the performance of the subject device

Substantial Equivalence

The modified GRAFTYS® QUICKSET has the same intended use/indications for use, principles of operation and technological characteristics as the cleared GRAFTYS® QUICKSET. The minor differences in the modified GRAFTYS® QUICKSET release specifications do not raise any new questions of safety or effectiveness. Thus, the modified GRAFTYS® QUICKSET is substantially equivalent to its predicate devices.

Conclusions

The modified GRAFTYS® QUICKSET is claimed to be substantially equivalent in terms of safety and effectiveness to the predicate GRAFTYS® QUICKSET as a resorbable calcium salt bone void filler device. The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. The indications for use of the subject device were not changed as a result of the modified specifications and the fundamental scientific technology of the device, including the bone void filler's mechanism of action, performance remains identical to the original product.