K093343

Graftys

GRAFTYS® Quickset
Resorbable Bone Void Filler
510(k) Summary

APR 22 2010

Prepared: October, 14, 2009

1. Submitter Information

Name :	GRAFTYS
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Contact:	Anthony LE NAOUR - Regulatory Manager

2. Name of Device

Trade Name:	GRAFTYS®QUICKSET
Common Name:	Resorbable calcium salt bone void filler device
Classification name:	Resorbable calcium salt bone void filler device (CFR 888.3045 ; Product Code : MQV)

3. Legally Marketed Predicate Device

Predicates	GRAFTYS®HBS - Resorbable calcium salt bone void filler device [K082498]

4. Device Description

GRAFTYS®QUICKSET is an injectable self-hardening macroporous synthetic calcium phosphate bone substitute. It comes in a double-compartment mixing 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 in approximately 2min, is then resorbed and replaced by bone. The injection is administered manually or using a delivery gun. GRAFTYS®QUICKSET is a sterile single-use product.

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5. Intended 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.

6. Technological characteristics

GRAFTYS®QUICKSET and the predicate GRAFTYS®HBS devices have the same intended use, the same principle of operation and very similar technological characteristics. The minor technological differences do not raise any new issues of safety or effectiveness.

7. Non clinical performance data

In vitro testing, performed 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, support the substantial equivalence between GRAFTYS®QUICKSET and the predicate device GRAFTYS®HBS.

8. Conclusion

GRAFTYS®QUICKSET is claimed to be substantially equivalent in term of safety and effectiveness to the predicate devices GRAFTYS®HBS as a resorbable calcium salt bone void filler device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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GRAFTYS
% Mr. Anthony Le Naour
Regulatory Affairs Manager
Eiffel Park – Bât D
415, rue Claude Nicolas Ledoux
13854 AIX EN PROVENCE Cedex3
France

APR 22 2010

Re: K093343
Trade/Device Name: GRAFTYS® Quickset
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: March 30, 2010
Received: March 30, 2010

Dear Mr. Le Naour:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

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

Enclosure

Statement of Indications for Use

510(k) Number (if known): **K093343**

Device Name:

GRAFTYS® Quickset

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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093343