K082498

Graftys

FEB 25 2009

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

Prepared: August 22nd, 2008

1. Submitter Information

Name :	GRAFTYS
Address :	Eiffel Park – Bât D 415, rue Claude Nicolas Ledoux- 13 854 AIX EN PROVENCE Cedex3 FRANCE
Telephone:	+ 33 (0) 4 42 60 30 00
Facsimile:	+ 33 (0) 4 42 60 30 11
Contact:	Anthony LE NAOUR - Regulatory Manager

2. Name of Device

Trade Name:	GRAFTYS®HBS
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

Predicate	NORIAN® SRS® - Resorbable calcium salt bone void filler device [K011897]

4. Device Description

GRAFTYS®HBS 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, 8cc of an injectable calcium-deficient apatite is athermally formed. In-vivo, this apatite which hardens in approximately 15 min, is then resorbed and replaced by bone. The injection is administered manually or using a delivery gun. GRAFTYS®HBS is a sterile, non-pyrogenic, single-use product.

G5

Graftys

5. Intended Use

GRAFTYS®HBS is intended for bony voids or defects that are not intrinsic to the stability of the bony structure. GRAFTYS®HBS is intended to be placed or injected into bony voids or gaps of the skeletal system (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®HBS and the predicate device NORIAN® SRS® 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 and in-vivo 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®HBS and the predicate device.

8. Conclusion

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

GRAFTYS – SARL au capital de 1 599 995 Euros – Siret 484 024 989 00028 – APE 244D
Eiffel Park – Bât D – 415, rue Claude Nicolas Ledoux – F-13 854 Aix en Provence Cedex 3, France
Tel : +33 (0)4 42 60 30 00 – Fax : + 33 (0)4 42 60 30 11 – contact@graftys.fr
www.graftys.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Graftys
% Mr. Anthony Le Naour
Regulatory Manager
415, rue Claude Nicolas Ledoux
F-13854 Aix en Provence Cedx3
France

FEB 2 5 2009

Re: K082498
Trade/Device Name: GRAFTYS® HBS
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable bone substitute
Regulatory Class: II
Product Code: MQV
Dated: January 30, 2009
Received: February 5, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Statement of Indications for Use

510(k) Number (if known):_____

Device Name:

GRAFTYS®HBS

Indications For use:

GRAFTYS®HBS is intended for bony voids or defects that are not intrinsic to the stability of the bony structure. GRAFTYS®HBS is intended to be placed or injected into bony voids or gaps of the skeletal system (the extremities and the 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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K092497