K130235

JAN 10 2014

510(k) SUMMARY

Submitter Name:	HansBiomed Corp.
Submitter Address:	8 Floor SK Building Seongsu 1-ga Seongdong-gu Seoul, 133-110 Korea
Contact Person:	Ms. Lucy Choi
Phone Number:	0082 2 466 2266
Fax Number:	0082 2 463 1554
Date Prepared:	January 30, 2013
Device Trade Name:	SurFuse™ II Putty, ExFuse™ II Putty
Device Common Name:	Bone grafting material, Human
Classification Number:	21 CFR 872.3930
Product Code and Classification Name	NUN Bone grafting material, human source
Device Class	II
Predicate Devices:	K113728, SurFuse™ Putty, ExFuse™ Putty, HansBiomed Corp K051188, GRAFTON® DBM, Osteotech, Inc. K091217, DBX Demineralized bone matrix putty, Musculoskeletal Transplant Foundation.
Indications for Use:	The SurFuse™II Putty and ExFuse™II Putty are bone filling materials indicated for dental intraosseous, oral and maxillofacial defects, including periodontal/infrabony defects; alveolar ridge augmentation; dental extraction sites; sinus lifts; cystic defects.
Device Description:	The SurFuse™II Putty and ExFuse™II Putty are derived from human allograft bone tissue that is processed into a powder and demineralized using a hydrochloric acid process. The demineralized bone matrix (DBM) is combined with a resorbable carrier, carboxymethylcellulose (CMC) and formulated into a putty-like consistency. The ExFuse™II Putty also contains cancellous bone powder. They are provided sterile for single patient use. The products are provided sterile for single patient use.

Serological Testing & Biocompatibility	The donor bone is obtained from AATB-certified tissue banks in the United States and the donor suitability criteria used to screen donors are in compliance with the FDA regulations published in 21 CFR Part 1270 and Part 1271 Human Tissue Intended for Transplantation. Further the manufacturing and sterilization processes were assessed for viral inactivation potency by a validation assessment, which included Human Immunodeficiency Virus-1 (HIV-1), Bovine Herpes Virus (BHV), Bovine Viral Diarrhea Virus (BVDV), Hepatitis A Virus (HAV) and Porcine Parvovirus (PPV). Biocompatibility testing, according to ISO 10993, has been performed and the devices have been shown to be non-toxic and biocompatible.
Performance:	The devices were tested to characterize their osteoconductive ability to grow bone *in vivo* in the dog alveolar bone model. They also have been tested *in vivo* in the athymic (nude) rat muscle pouch model and were shown to have osteoinductive potential, in that new bone grew within the muscle tissue. The osteoinductive potential also was evaluated with a surrogate, *in vitro* BMP-2 ELISA, assay. Results from that assay were correlated with results from the same lots in which bone successfully formed in the athymic rat. Each lot of the SurFuse™ II and ExFuse™ II devices will be evaluated for osteoinductive potential using the *in vitro* assay. Osteoinduction assay results observed in surrogate assessments should not be interpreted to predict clinical performance in human subjects.
Comparison to the Predicate Devices:	The SurFuse™II and ExFuse™II devices, with respect to Intended Use as bone void fillers, are the same as the both predicate families of devices; and with respect to the *Indications for Use* to augment intraosseous, oral and maxillofacial defects, are the same as the Grafton® DBM predicate. The SurFuse™II and ExFuse™II devices are identical in all respects including composition, processing, manufacturing and packaging to the parent predicate SurFuse™ II and ExFuse™ II devices and substantially equivalent in material composition and device characteristics to the Grafton® DBM predicate.
Substantial Equivalence Conclusion	The comparisons and study data presented in the 510(k) lead to the conclusion that the SurFuse™II Putty and ExFuse™II Putty are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2014

HansBiomed Corporation
C/O Ms. Patsy J. Trisler, JD, RAC
Regulatory Consultant
Trisler Consulting
5600 Wisconsin Ave., #509
Chevy Chase, MD 20815

Re: K130235
Trade/Device Name: SurFuse™ II Putty, ExFuse™ II Putty
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material
Regulatory Class: II
Product Code: NUN
Dated: December 5, 2013
Received: December 11, 2013

Dear Ms. Trisler:

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.

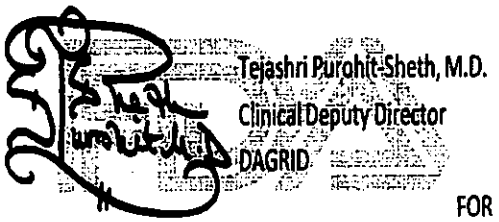
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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. 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

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130235

Device Name: SurFuse™II Putty
ExFuse™II Putty

Indications for Use:

The SurFuse™II Putty and ExFuse™II Putty are bone filling materials indicated for dental intraosseous, oral and maxillofacial defects, including periodontal/infrabony defects; alveolar ridge augmentation; dental extraction sites; sinus lifts; cystic defects.

Prescription Use __X_
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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