February 22, 2018

Hans Biomed Corporation
% Patsy J. Trisler, JD, RAC
Regulatory Consultant
Trisler Consulting
5600 Wisconsin Avenue, #509
Chevy Chase, Maryland 20815

Re: K171568
Trade/Device Name: SurFuse™ Gel, SurFuse™ Putty, ExFuse™ Gel, ExFuse™ Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: January 12, 2018
Received: January 16, 2018

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171568

Device Name

SurFuse™ Gel, SurFuse™ Putty, ExFuse™ Gel, ExFuse™ Putty

Indications for Use *(Describe)*

SurFuse™ Gel, SurFuse™ Putty, ExFuse™ Gel, ExFuse™ Putty products are indicated for bony voids or gaps that are not intrinsic to the stability of the bone structure. They are intended to be gently packed into bony voids or gaps of the skeletal system as a bone void filler in the extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. These products resorb and are 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.

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

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Section 5.0
510(k) SUMMARY

Submitter Name:	Hans Biomed Corp.
Submitter Address:	64, Yuseong-daero 1628beon-gil, Yuseong-gu, Daejeon, Republic of Korea
Contact Person:	Ms. Lucy Choi
Phone Number:	82 2 466 2266
Fax Number:	82 2 463 1554
Date Prepared:	May 30, 2017
Device Trade Name:	SurFuse™ Gel, SurFuse™ Putty, ExFuse™ Gel, ExFuse™ Putty
Device Common Name:	Resorbable Calcium Salt Bone Void Filler Device
Classification Number:	21 CFR 888.3045
Product Code:	MQV, MBP
Classification Name:	Filler, bone void, calcium compound
Device Class:	II
Predicate Devices:	Primary: K103784, DBX® Demineralized Bone Matrix Putty, Musculoskeletal Transplant Foundation Reference: K113728, SurFuse™ Gel, SurFuse™ Putty, ExFuse™ Gel, ExFuse™ Putty, Hans Biomed Corp.
Statement of Intended Use:	SurFuse™ Gel, SurFuse™ Putty, ExFuse™ Gel, ExFuse™ Putty products are indicated for bony voids or gaps that are not intrinsic to the stability of the bone structure. They are intended to be gently packed into bony voids or gaps of the skeletal system as a bone void filler in the extremities and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. These products resorb and are replaced with bone during the healing process.
Device Description	**Device Identification and Materials of Use:** The submitted devices are resorbable bone void filler, combining Human Demineralized Bone Matrix (DBM) with cancellous bone powder and carboxymethylcellulose (CMC). The primary component of SurFuse™ and ExFuse™ is demineralized particle bone which is derived from human donor cortical bone. The additional bone powder in the ExFuse™ is derived from human donor cancellous bone. The CMC is added to enhance the cohesiveness of the composition.

Device Characteristics:
The submitted devices are provided in several volumes ranging from 0.3cc to 10 cc. The devices are supplied sterile for single patient use.

Body Contact:
The submitted devices are a permanent resorbable device, implanted in bone tissue.

Mechanism of Action:
The submitted devices resorb over time and remodel providing an osteoconductive scaffold for regeneration of new bone. In addition, because the devices are composed primarily of DBM, they have osteoinductive potential.

Environment of Use:
The submitted devices are for use only in institutional health care or hospital environments.

Serological Testing & Biocompatibility:

The donor bone is obtained from AATB-certified tissue banks in the United States and screened for:

- antibodies to the human immunodeficiency virus, type1 and type2 (anti- HIV-1 and anti-HIV-2);
- nucleic acid test (NAT) for HIV-1;
- hepatitis B surface antigen (HBsAg);
- nucleic acid test (NAT) for the hepatitis B virus (HBV);
- total antibodies to hepatitis B core antigen (anti-HBc—total, meaning IgG and IgM);
- antibodies to the hepatitis C virus (anti-HCV);
- nucleic acid test (NAT) for HCV; and
- syphilis (a non-treponemal or treponemal-specific assay may be performed)

The manufacturing and sterilization processes were assessed for viral inactivation potency by a validation assessment which includes Human Immunodeficiency Virus-1 (HIV-1), Bovine Herpes Virus (BHV), Bovine Viral Diarrhea Virus (BVDV), Hepatitis A Virus (HAV) and Porcine Parvovirus (PPV). The validation assessment observed complete inactivation of inoculated viral titers.

Biocompatibility testing, according to ISO 10993, has been performed and the device has been shown to be safe, non-toxic and biocompatible.

Performance:

Osteoconduction and Performance as a Bone Void Filler:
The submitted devices were tested successfully to fully assess the performance to grow bone in the *in vivo* rabbit unicortical defect model.

Osteoinductive Potential:
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 device 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 submitted devices have the same intended use as the primary predicate device.

The devices contain the same base osteoconductive material, DBM, as all predicate devices. They are provided in a syringe package and contain an additional carrier, as all predicate devices.

The submitted devices are manufactured in the same facility and sterilized in the same establishment as the supporting predicate devices, SurFuse™ Gel & Putty and ExFuse™ Gel & Putty (K113728).

Substantial Equivalence Conclusion:

The comparisons summarized above and the study data presented in the 510(k) lead to the conclusion that the submitted bone void filler devices are substantially equivalent to the primary and supporting predicate devices.