DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 22, 2016

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

Re: K151271
Trade/Device Name: BellaFuse™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: February 1, 2016
Received: February 1, 2016

Dear Ms. Trisler:

This letter corrects our substantially equivalent letter of March 11, 2016.

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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

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)*
K151271

Device Name

BellaFuse™

Indications for Use *(Describe)*

BellaFuse™ is an implant intended to fill bony voids or gaps of the skeletal system i.e., posterolateral spine. These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. BellaFuse™ 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.

Section 5.0
510(k) SUMMARY

Submitter Name:	Hans Biomed Corp.
Submitter Address:	64, Yuseong-Daero 1628Beon-Gil, Yuseong-Gu, Korea, Republic of, 305-811
Contact Person:	Ms. Lucy Choi
Phone Number:	0082 2 466 2266
Fax Number:	0082 2 463 1554
Date Prepared:	May 13, 2015
Device Trade Name:	BellaFuse™
Device Common and Classification Name:	Resorbable Calcium Salt Bone Void Filler
Classification Number:	21 CFR 888.3045
Product Code:	MQV, MBP
Device Class:	II
Predicate Devices:	Primary: K043421, RTI Allograft Strip IC, Regeneration Technologies, Inc. K062205, DBX® Strip, Musculoskeletal Transplant Foundation K113728, SurFuse™ Gel & Putty, ExFuse™ Gel & Putty, Hans Biomed Corp.
Indications for Use Statement:	The BellaFuse™ is an implant intended to fill bony voids or gaps of the skeletal system, i.e. posterolateral spine. These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Bellafuse™ resorbs and is replaced with bone during the healing process.
DEVICE DESCRIPION:	**Device Identification and Materials of Use:** BellaFuse™ is a resorbable bone void filler, combining Human Demineralized Bone Matrix (DBM) with gelatin. The primary component of this BVF product is demineralized particle bone, which is derived from human donor cortical bone. The additional porcine gelatin is a biocompatible component which maintains the shape and enhances flexibility. **Device Characteristics:** This product is provided in several flexible sheet sizes ranging from 10x10x2.5mm to 50x100x5.0mm. It is supplied sterile for single patient use. **Body Contact:** BellaFuse™ is a permanent resorbable device, implanted in bone tissue.

Mechanism of Action:

This device resorbs over time and remodels providing an osteoconductive scaffold for regeneration of new bone. In addition, because it is composed primarily of DBM, it has osteoinductive potential.

Environment of Use:

BellaFuse™ is for use only in institutional health care or hospital environments.

SUMMARY OF TESTING:

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, Type 1 and Type 2 (anti-HIV-1 and anti-HIV-2);
- Nucleic Acid Test (NAT) for HIV-1;
- Hepatitis B Surface Antigen (HBsAg);
- Total antibodies to Hepatitis B core antigen (anti-HBc-total);
- Antibodies to the Hepatitis C Virus (anti-HCV);
- Nucleic Acid Test (NAT) for HCV;
- Syphilis

The manufacturing and sterilization processes were assessed for viral inactivation potency by a validation assessment for viral inactivation test Transmissible gastroenteritis virus (TGEV), Pseudorabies virus (PRV), Porcine retavirus (PRoV), Porcine Parvovirus (PPV), Hepatitis A virus (HAV). 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:

BellaFuse™ was tested successfully to fully assess the performance to grow bone in the *in vivo* rabbit spinal model.

Osteoinductive Potential:

The devicehas been tested *in vivo* in the athymic (nude) rat muscle pouch model and was 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 BellaFuse™ device will be evaluated for osteoinductive potential using the *in vitro* assay.

Osteoinductive assay results observed in surrogate assessments should not be interpreted to predict clinical performance in human subjects.

COMPARISON TO PREDICATE DEVICES:

BellaFuse™ has the same intended use as all predicate devices.

It contains the same base osteoconductive material, DBM, as all predicates.

It is provided in the same flexible sheet/strip form and contains the same porcine gelatin, as the primary RTI Allograft Strip IC and supporting predicate DBX® Strip predicates.

It is manufactured in the same facility and is sterilized the same as the third predicate, SurFuse™ Gel & Putty, ExFuse™ Gel & Putty.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

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