Section 5.0
510(k) SUMMARY

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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.