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

February 16, 2017

Amend Surgical, Inc.
% Lisa Simpson
Regulatory Consultant
Simpson Regulatory Solutions, LLC
4401 NW 18 Place
Gainesville, Florida 32605

Re: K161996
Trade/Device Name: 0.5cc NanoFUSE®, 1.0cc NanoFUSE®, 2cc NanoFUSE®, 5cc NanoFUSE®, 10cc NanoFUSE®
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: January 13, 2017
Received: January 17, 2017

Dear Ms. Simpson:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

INDICATIONS FOR USE

510(k) Number (if known): K161996

Device Name: NanoFUSE®

Indications for Use:

NanoFUSE® is indicated to be gently placed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure (i.e. the posterolateral spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NanoFUSE® must be used with autograft as a bone graft extender in the posterolateral spine and pelvis. The product provides a bone graft substitute that remodels into the recipient's skeletal system.

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)

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Device: NanoFUSE®

Date: January 13, 2017

Submitted by:
Amend Surgical, Inc.
13859 Progress Blvd., Suite 600
Alachua, FL 32615
Ph: (844) 281-3169
Fax: n/a

Regulatory Representative:
Lisa C. Simpson
(consultant)
Simpson Regulatory Solutions, LLC
4401 NW 18 Place
Gainesville, FL 32605

Proprietary Name: NanoFUSE®

Common Name: Bone Void Filler, Bone Graft Substitute

Classification Name: Resorbable calcium salt bone void filler device

Regulation: 21 CFR § 888.3045

Classification Code: MQV - Class II

Predicate Devices:

Trade/Proprietary Name	Manufacturer	510(k) Number
NanoFUSE® DBM (primary predicate)	Amend Surgical, Inc. / Nanotherapeutics, Inc.*	K142104
NovaBone Putty – Bioactive Synthetic Bone Graft (reference predicate)	NovaBone Products, LLC	K110368
**Device was cleared by NanoTherapeutics, Inc. Subsequently, 510(k) ownership was transferred to Amend Surgical, Inc. per a contractual agreement.*		

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Description:
NanoFUSE® is a malleable, putty-like, bone-void filler. The product is comprised of a synthetic calcium phosphor-silicate particulate material particles (45S5 bioactive glass), both coated with gelatin derived from porcine skin. These coated particles are packaged dry in a single use, medical grade polymer syringe, double-wrapped in peel-back pouches, in a dust cover paperboard carton. An empty sterile syringe for addition of the hydration fluid of choice is also included in the sterile barrier packaging. NanoFUSE® is intended for single patient use only and is non-pyrogenic. Instructions for use are provided by way of a package insert in the paperboard carton.

At point of use, the surgeon reconstitutes the product with an appropriate sterile solution of choice (sterile saline, water for injection, or autologous whole blood). The coated particles rehydrate in less than 30 seconds and do not require mixing to form a uniform paste or putty. The material is then mixed with autograft and gently extruded by the surgeon into the bone void. NanoFUSE® is progressively resorbed and replaced by host bone during the osteo-remodeling process.

Indications for Use:
NanoFUSE® is indicated to be gently placed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure (i.e. the posterolateral spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. NanoFUSE® must be used with autograft as a bone graft extender in the posterolateral spine and pelvis. The product provides a bone graft substitute that remodels into the recipient's skeletal system.

Technological Characteristics:
NanoFUSE® is comprised of synthetic calcium phosphor-silicate particulate material particles (45S5 bioactive glass) coated with gelatin derived from porcine skin. It is provided dry and is reconstituted at the point of use into a paste-like, malleable form that can be molded or manipulated into bony defects.

The bioactive glass and gelatin binder in NanoFUSE® is identical to that utilized for the legally marketed primary predicate device (K142104, NanoFUSE® DBM). However, NanoFUSE® DBM incorporates demineralized bone matrix (DBM) whereas the NanoFUSE 510(k) subject device does not.

Both NanoFUSE® and NanoFUSE DBM contain 45S5 bioactive glass and an inert carrier. NanoFUSE DBM is designated as the primary predicate device and was used as a comparative control for *in vivo* studies in the rabbit.

NanoFUSE® is reconstituted by the addition of fluid of choice (sterile saline, water for injection or autologous whole blood). The product extrudes as a very fluid paste and, with

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510(K) SUMMARY OF SAFETY & EFFECTIVENESS

time, the gelatin carrier absorbs the fluid, becomes progressively thicker, and eventually sets in a rubbery mass.

Comparison Feature	**NanoFUSE® DBM Primary Predicate K142104**	**NanoFUSE® 510(k) Subject Device**	**NovaBone Putty Reference Predicate K110368**
Materials of Construction	45S5 bioactive glass Porcine Gelatin Demineralized Bone Matrix (DBM)	45S5 bioactive glass Porcine Gelatin	45S5 bioactive glass Synthetic Binder
Sizes	2cc to 10cc	0.5cc to 10cc	1cc to 10cc
Packaging Forms	Syringe	Syringe	Clamshell Tray Syringe Jar
How Provided	Sterile Single Use	Sterile Single Use	Sterile Single Use
Preparation	Hydrate with sterile saline, water for injection (WFI), or autologous whole blood.	Hydrate with sterile saline, water for injection (WFI), or autologous whole blood.	Ready to Use (no hydration needed)
Anatomic Sites	Posterolateral Spine Pelvis Extremities	Posterolateral Spine Pelvis	Posterolateral Spine Pelvis Extremities
Intended for use with autograft?	Yes	Yes	Optional
Mode of Action	Mode of Action: *45S5 Bioactive Glass*: Osteoconductive Scaffold *DBM*: Osteoinductive Potential	Mode of Action: *45S5 Bioactive Glass*: Osteoconductive Scaffold	Mode of Action: *45S5 Bioactive Glass*: Osteoconductive Scaffold

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Safety and Effectiveness:
The device is provided sterile, for single use only and has a one-year shelf life. Biocompatibility data from the NanoFUSE® DBM primary predicate device (K142104) was adopted for the NanoFUSE® 510(k) subject device as the NanoFUSE® DBM includes the same 45S5 bioactive glass and porcine gelatin. Also, the packaging for NanoFUSE® DBM is the same as the proposed NanoFUSE device. The use of NanoFUSE® in the posterolateral spine was evaluated *in vivo* in the rabbit model. Two studies (24 weeks and 52 weeks) demonstrate the device performance is substantially equivalent to the comparative control, NanoFUSE DBM (K142104). These studies further support the biocompatibility of the NanoFUSE® device.

Substantial Equivalence:
The bioglass and porcine gelatin in NanoFUSE® are identical to those utilized for the primary predicate device, NanoFUSE® DBM (K142104). NanoFUSE® and NanoFUSE® DBM (K142104) have the same packaging and both devices are labeled as non-pyrogenic. NanoFUSE® is not indicated for use in the extremities as are the predicate devices; therefore, the indications for use relative to NanoFUSE® DBM (K142104) were modified accordingly.

NanoFUSE® is similar in formulation to NovaBone Putty (K110368) as both include 45S5 bioactive glass and an inert carrier to facilitate handling; neither device contains DBM. The proposed NanoFUSE device, NanoFUSE® DBM predicate (142104) and NovaBone Putty predicate (K110368) are all provided sterile, for single use only and are intended for use in the posterolateral spine and pelvis.

NanoFUSE DBM (K142104) was chosen as the comparative control for posterolateral spine studies in the rabbit because the formulation contains the same bioglass and gelatin constituents. Both the 24-week study and 52-week rabbit spine study results demonstrate NanoFUSE® *in vivo* performance to be substantially equivalent to NanoFUSE DBM (K142104), in consideration that the predicate device includes DBM, which provides an osteoinductive advantage.

Based on the composite of descriptive information and supporting animal data, NanoFUSE® is deemed substantially equivalent to NanoFUSE DBM (K142104), the primary predicate device, when used as a bone graft extender, in accordance with the indications for use and instructional information provided in the device labeling.