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

May 6, 2016

HT Medical, LLC
% Nicholas Cordaro
President
Additive Innovations, LLC
533 2nd Street, Suite A
Encinitas, California 92024

Re: K153615
Trade/Device Name: NeoFuse™ HA Enhanced PLIF/TLIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 16, 2016
Received: April 18, 2016

Dear Mr. Cordaro:

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 Parts 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" (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 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)*
K153615

Device Name
NeoFuse™ HA Enhanced PLIF/TLIF

Indications for Use *(Describe)*
When used as a Lumbar Interbody Fusion device, NeoFuse is indicated for use in skeletally mature patients with DDD at one or two contiguous levels from L2-S1. Lumbar DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received at least six (6) months of prior non-operative treatment prior to treatment with the device.

The devices must be used with supplemental fixation and must be used with autograft / autologous bone graft to facilitate fusion for each spinal region.

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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5. 510(k) Summary

HT Medical LLC's

NeoFuse™ HA Enhanced PLIF/TLIF

Intervertebral Body Fusion System

Trade Name:	NeoFuse™ HA Enhanced PLIF/TLIF
Common Name:	Intervertebral Body Fusion Device
Product Class:	Class II
Classification:	888.3080
Product Code:	MAX (Lumbar)
Panel Code:	87 Orthopedic
Date Prepared:	**May 5, 2016**

Sponsor / Manufacture Information:

HT Medical, LLC
Attn: Robert Compton
6316 E 102nd Street
Tulsa, OK 74137
Phone: 417-309-9457
Registration Number: PENDING

Contact Information:

Additive Innovations, LLC
Attn: Nicholas Cordaro
533 2nd Street, Suite A
Encinitas, CA 92024
Phone: 760-525-9900

Device Description

The NeoFuse™ HA Enhanced PLIF/TLIF devices are intervertebral body fusion devices made from PEEK-OPTIMA HA Enhanced (HA PEEK). Each device may include an optional Titanium Insert containing through holes to increase graft volume. The implants are available in various heights and lengths to accommodate patients' anatomy. The implants are provided non-sterile with surgical instruments to facilitate implantation. Radiographic markers made of tantalum (ASTM F-560), or titanium alloy (ASTM F-136) are included in each implant to allow radiographic visualization.

Predicate Device

The interbody fusion system is substantially equivalent to legally marketed predicate devices. The primary predicate devices is Depuy/AcroMed Lumbar I/F Cage per P960025, with additional predicates including Meditech Spine Talos-C per K142345, SpineFrontier, Inc., Arena-C HA PEEK Cervical Interbody Fusion Device per K142026, and Cutting Edge Spine, LLC's EVOS Lumbar Interbody System per K150321.

Intended Use / Indications for Use

When used as a Lumbar Interbody Fusion device, NeoFuse is indicated for use in skeletally mature patients with DDD at one or two contiguous levels from L2-S1. Lumbar DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should have received at least six (6) months of prior non-operative treatment prior to treatment with the device.

The devices must be used with supplemental fixation and must be used with autograft / autologous bone graft to facilitate fusion for each spinal region.

Technology Characteristics

The technological characteristics of the NeoFuse are equivalent or similar to the predicate devices, including the materials. Identical to K142345, K142026, and K150321 the hydroxyapatite filled polyetheretherketone (HA PEEK) contains HA which is a naturally occurring mineral in bone and is widely used in the orthopedic field. Similar to K142026, the devices are supplied non-sterile for steam sterilization. NeoFuse has the same technology characteristics and intended use as the intervertebral body fusion predicate devices P960025, K142345, K142026, and K150321.

Summary of Non-clinical Testing

The interbody fusion system was tested according to ASTM F2077 and ASTM F2267. Testing included static and dynamic axial compression, static and dynamic compression shear, static torsion, subsidence, and expulsion.

Test results demonstrated that the devices are substantially equivalent to the predicate devices.

Conclusion

Performance bench testing and comparisons have demonstrated NeoFuse is substantially equivalent to the predicate devices in regards to Indications for Use, Dimensions, Function, Materials, Mechanical Testing, and Technology Characteristics. The NeoFuse does not raise new questions of safety and effectiveness; and NeoFuse demonstrates substantial equivalence to legally marketed predicate devices.