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

July, 12, 2017

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

Re: K170318
Trade/Device Name: NeoFuse™ Ti3D PLIF/TLIF/Cervical Interbody
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: June 12, 2017
Received: June 14, 2017

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 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,

Vincent J. Devlin -S
for

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)*

K170318

Device Name

NeoFuse™ Ti3D PLIF/TLIF/Cervical Interbody

Indications for Use *(Describe)*

When used as a Lumbar Interbody Fusion device, NeoFuse Ti3D is indicated for use in skeletally mature patients with DDD at one or two contiguous levels from L2-S1. 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.

When used as a Cervical Interbody Fusion device, NeoFuse Ti3D is indicated for use in skeletally mature patients with cervical degenerative disc disease (DDD) at one level or two contiguous levels from C2 to T1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received six (6) weeks 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 and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion.

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.

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510(k) Summary

DATE PREPARED
January 26, 2017

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
NeoFuse™ Ti3D PLIF/TLIF/Cervical Interbody

COMMON NAME
Intervertebral body fusion device

DEVICE CLASSIFICATION
Intervertebral body fusion device
(21 CFR 888.3080, Product Codes ODP and MAX, Class II)

PREMARKET REVIEW
ODE/DOD/ASDB
Orthopedic Panel

INDICATIONS FOR USE
When used as a Lumbar Interbody Fusion device, NeoFuse Ti3D is indicated for use in skeletally mature patients with DDD at one or two contiguous levels from L2-S1. 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.

When used as a Cervical Interbody Fusion device, NeoFuse Ti3D is indicated for use in skeletally mature patients with cervical degenerative disc disease (DDD) at one level or two contiguous levels from C2 to T1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received six (6) weeks 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 and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion.

DEVICE DESCRIPTION

The NeoFuse Ti3D PLIF/TLIF/Cervical devices are intervertebral body fusion devices made from additive manufactured (AM) Titanium Grade 23 per ASTM F136. The implants are available in various heights and lengths to accommodate patients' anatomy. The implants are provided sterile.

PREDICATE DEVICE IDENTIFICATION

The NeoFuse Ti3D PLIF/TLIF/Cervical Interbody will be shown to be substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K160125	Cascadia Interbody System	✓
K153615	NeoFuse HA Enhanced PLIF/TLIF	
P960025	Lumbar I/F Cage	
K120275	DePuy Synthes ACIS	

SUMMARY OF NON-CLINICAL TESTING

FDA performance standards have been established for the NeoFuse Ti3D PLIF/TLIF/Cervical Intervertebral Body Fusion Device. The following tests were independently performed on the lumbar and cervical devices to demonstrate safety based on current industry standards:

- Static and dynamic axial compression (per ASTM F2077)
- Static torsion (per ASTM F2077)
- Static compression shear (per ASTM F2077)
- Subsidence (per ASTM F2267)
- Static Expulsion (per ASTM draft standard F04.25.02.02)

The cervical devices were additionally tested per:

- Dynamic torsion (per ASTM F2077)

The lumbar devices were additionally tested per:

- Dynamic compression shear (per ASTM F2077)

The effectiveness of the gamma irradiation as a means of sterilization for the cervical and lumbar devices was validated using AAMI/ANSI/ISO 11137-2 – method VD_{max}^{25}. This included:

- Bioburden recovery factor testing
- Bacteriostasis and fungistasis
- Bioburden
- Verification dose
- Sterility testing of the verification dose sample

The effectiveness of the final ultrasonic cleaning procedure for gamma sterilization included the following process qualifications:

- Visual verification
- Bioburden testing
- Cytotoxicity testing
- UV/Vis testing
- Total organic carbon (TOC)
- Bacterial Endotoxin (LAL)

The effectiveness of the packaging and shipping of sterile product included the following process qualifications:

- Shipping testing
- Peel strength testing
- Bubble emission testing
- Integrity inspections

The results of these tests indicated that the NeoFuse Ti3D PLIF/TLIF/Cervical Interbody is substantially equivalent to the predicate devices.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

HT Medical believes that the NeoFuse Ti3D PLIF/TLIF/Cervical Interbody has been shown to be substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimensions, intended use and similar technology characteristics as the devices cleared in K160125, K153615, and P960025. The subject device has an identical manufacturing method as the device cleared in K160125. The device has shown to have equivalent strength characteristics as the cleared predicate devices.

CONCLUSION

The NeoFuse Ti3D PLIF/TLIF/Cervical Interbody is considered substantially equivalent to the predicate devices based on the testing performed, the identical indications for use, and similar technological characteristics. Based on the testing performed, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicates.