September 1, 2023

HT Medical d.b.a. Xenix Medical
℅ Justin Eggleton
Vice President, Spine Regulatory Affairs
MCRA
803 7th Street NW, 3rd Floor
Washington, District of Columbia 20001

Re: K222988
Trade/Device Name: newWave LS Lumbar Straight, newWave C Cervical, and Ti3D Cervical
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: August 2, 2023
Received: August 2, 2023

Dear Justin Eggleton:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222988

Device Name

neoWave LS Lumbar Straight

Indications for Use *(Describe)*

The neoWave LS Porous Titanium Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). neoWave LS Porous Titanium Cage implants are to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft implanted via a transforaminal approach or an open posterior approach. The neoWave LS Porous Titanium Cage implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device

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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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222988

Device Name
neoWave C Cervical

Indications for Use *(Describe)*

The neoWave C Porous Titanium Cage is intended 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)

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Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222988

Device Name
Ti3D Cervical

Indications for Use *(Describe)*

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)

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510(k) Summary

Device Trade Name: neoWave LS Lumbar Straight, neoWave C Cervical, and Ti3D Cervical

Manufacturer: HT Medical, LLC d.b.a. Xenix Medical
111 W Jefferson St., Suite 100
Orlando, FL 32801

Contact: Teresa Cherry
Vice President of Quality Assurance and Regulatory Affairs
Xenix Medical

Prepared by: Mr. Justin Eggleton
Vice President, Head of Musculoskeletal Regulatory Affairs
MCRA, LLC
803 7th Street NW, 3rd Floor
Washington, DC 20001
jeggleton@mcra.com

Date Prepared: August 31, 2023

Classifications: 21 CFR §888.3080; Intervertebral body fusion device

Class: II

Product Codes: ODP, MAX

Purpose of the Submission:

The purpose of the subject 510(k) was to add a nanotechnology claim in alignment with the FDA's Guidance on Nanotechnology and to request an additional/change in AM manufacturer.

Indications for Use:

neoWave LS Lumbar Straight

The neoWave LS Porous Titanium Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). neoWave LS Porous Titanium Cage implants are to be used with autogenous bone graft and/or allograft comprised of cancellous and/or corticocancellous bone graft implanted via a transforaminal approach or an open posterior approach. The neoWave LS Porous Titanium Cage implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to

treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

neoWave C Cervical

The neoWave C Porous Titanium Cage is intended 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.

Ti3D Cervical

When used as a Cervical Interbody Fusion device, Ti3D Cervical 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:

neoWave LS Lumbar Straight

Xenix Medical neoWave LS Lumbar Straight Cages are intervertebral body fusion devices intended for use in the lumbar spine and made from additive manufactured (AM) Titanium Grade 23 per ASTM F3001. The implants are available in 6-17mm heights and various footprints to accommodate patient anatomy. The implants are provided sterile.

Devices incorporate Xenix Medical's proprietary NANOACTIV micro and nano-roughened surface designed to improve fixation to adjacent bone. The Xenix Medical implant surfaces have been engineered with surface features at a nanometer (10^{-9}) level, which have demonstrated the ability to elicit an endogenous cellular and biochemical response as represented by mineralization in human mesenchymal stem cells *in vitro*. The implant surface demonstrates elements to be considered a nanotechnology as outlined in the FDA nanotechnology guidance document.

neoWave C Cervical

Xenix Medical neoWave C Cervical Cage is intervertebral body fusion device intended for use in the cervical spine and made from additive manufactured (AM) Titanium Grade 23 per ASTM F3001. The implants are available in 4-12mm heights and various footprints to accommodate patient anatomy. The implants are provided sterile.

Devices incorporate Xenix Medical's proprietary NANOACTIV micro and nano-roughened surface designed to improve fixation to adjacent bone. The Xenix Medical implant surfaces have been engineered with surface features at a nanometer (10^{-9}) level, which have demonstrated the

ability to elicit an endogenous cellular and biochemical response as represented by mineralization in human mesenchymal stem cells *in vitro*. The implant surface demonstrates elements to be considered a nanotechnology as outlined in the FDA nanotechnology guidance document.

Ti3D Cervical
Xenix Medical Ti3D Cervical Cages are intervertebral body fusion devices intended for use in the cervical spine and made from additive manufactured (AM) Titanium Grade 23 per ASTM F3001. The implants are available in 4-12mm heights and various footprints to accommodate patient anatomy. The implants are provided sterile.

Devices incorporate Xenix Medical's proprietary NANOACTIV micro and nano-roughened surface designed to improve fixation to adjacent bone. The Xenix Medical implant surfaces have been engineered with surface features at a nanometer (10^{-9}) level, which have demonstrated the ability to elicit an endogenous cellular and biochemical response as represented by mineralization in human mesenchymal stem cells *in vitro*. The implant surface demonstrates elements to be considered a nanotechnology as outlined in the FDA nanotechnology guidance document.

Predicate Devices:

Table 1: Predicate Devices

Device Name(s)	Manufacturer	K-Number
Primary Predicate Device		
TiWAVE-L Porous Titanium Lumbar Cage (TiWAVE-L)	Kalitec Direct, LLC	K182210
Additional Predicate Devices		
TiWAVE-C™ Porous Titanium Cervical Cage (TiWAVE-C)	Kalitec Direct, LLC	K180401
Ti3D Cervical (NeoFuse Cervical)	HT Medical, LLC	K170318

Performance Testing Summary:

In consideration of the FDA's Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, in vitro evaluations and imaging studies were performed to assess that the deliberately modified NANOACTIV surface produces micro and nano surface roughness ranging in size between 1-100 nanometers, which exhibit specific osteogenic differentiation. The in vitro study results demonstrated the modified NANOACTIV nanosurface as supporting differentiation of mesenchymal stem cells through the osteogenic lineage and production of a mineralized matrix as compared to a non-treated surfaces.

In addition to the testing described above, confirmatory mechanical testing per ASTM F2077 was performed to support the change in AM supplier. ASTM F2077 testing was performed on the cervical (dynamic axial compression, dynamic torsion) and lumbar (dynamic axial compression, dynamic compression shear) versions of the devices.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicate cited in the passage above with respect to indications, design, materials, function, manufacturing, and performance.

Conclusion:
The Xenix Medical Interbody Cage devices are substantially equivalent to the cited predicate devices with respect to indications for use, design, function, materials, and performance.