September 19, 2024

Next OrthoSurgical
% Chhavy Tep-Cullison
Regulatory Affairs Specialist
JALEX Medical
27865 Clemens Rd, Suite 3
Westlake, Ohio 44145

Re: K242509
Trade/Device Name: HA*nano* InterFuse® Modular Interbody
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 22, 2024
Received: August 22, 2024

Dear Chhavy Tep-Cullison:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Katherine D. Kavlock -S

for
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)*
K242509

Device Name
HAnano InterFuse® Modular Interbody

Indications for Use *(Describe)*
The HAnano InterFuse® Modular Interbody is intended to be used for spinal fusion procedures in skeletally mature patients with degenerative disc disease (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 patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The HAnano InterFuse® device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The HAnano InterFuse® device is indicated for use with autogenous bone graft, and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

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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510(k) Summary

Applicant: Next Orthosurgical
3270 Corporate View, Suite A
Vista, CA 92081

Date: 09/09/2024

Applicant Contact: Misty Calkins
Sr. RA/QA Specialist
MCalkins@nextorthosurgical.com

Contact Person: Chhavy Tep-Cullison
Regulatory Affairs Specialist, JALEX Medical
Contact Email: ccullison@jalexmedical.com
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Regulation Number: 21 CFR 888.3080

Classification Product Code: MAX

Device Trade Name: **HA*nano* InterFuse® Modular Interbody**
Common Name: Intervertebral body fusion device
Device Classification Name: Intervertebral fusion device with bone graft, lumbar
Device Class: II
Reviewing Panel: Orthopedic

Primary Predicate Device: **K091988 – InterFuse® Intervertebral Body Fusion Device**
Additional Predicates: K222561 – Align Intervertebral Body Fusion Device
K201614 – AxTiHA™ Stand-Alone ALIF System

Device Description:
The HA*nano* InterFuse® Modular Interbody is a modular lumbar intervertebral body fusion device with an implantable portion composed of polyetheretherketone (PEEK), a polymer with a history of use in interbody fusion device designs, and which has a compressive modulus similar to bone. This device is designed to be implanted via a PLIF approach utilizing a minimally invasive surgical technique to restore collapsed/afflicted disc space. The device construct consists of an initial A module, any number of middle B modules to appropriately fill the interbody space, and a final C module in which each module interlocks with the adjacent module(s). These modules are inserted via a rail system in which a PEEK and stainless steel tail attached to each module extends beyond the disc space and allows the modules to be inserted in a sequential fashion. The PEEK portion of the tail can be detached, which detaches the entire rail and allows the modules to be progressed laterally in the disc space and repeated to construct the implant in an in situ

fashion. The modules will be manufactured in several different size/lordotic options to appropriately accommodate patient pathologies.

Indications for Use and Intended Use:

The HA*nano* InterFuse® Modular Interbody is intended to be used for spinal fusion procedures in skeletally mature patients with degenerative disc disease (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 patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The HA*nano* InterFuse® device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The HA*nano* InterFuse® device is indicated for use with autogenous bone graft, and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

Description of Modifications:

The purpose of this submission is for Next Orthosurgical to obtain clearance for the HA*nano* InterFuse® Modular Interbody line extension, which includes an updated surface treatment of the legally marketed previous generation of the device, the Interfuse® Intervertebral Body Fusion Device (K091988). HA*nano* surface treatment from Promimic AB will be applied to the entire surface of the PEEK implants. This product will aim to optimize both the mechanical properties of PEEK interbodies for lumbar fusion as well as the bone integrating qualities of HA that raw PEEK would not previously exhibit. There are no changes to material or sterilization parameters. The substrate material, articulating geometry, articulating surface roughness, porous coating and bone-facing geometry are identical to the InterFuse® Intervertebral Body Fusion Device.

Special 510(k) Submission – HA*nano* InterFuse® Modular Interbody
510(k) Summary

Summary of Technological Characteristics:
The subject HA*nano* InterFuse® Modular Interbody has the same intended use and indications for use as the predicate system. The technological characteristics of the subject system are similar to those of the predicate, and the information provided herein demonstrates that any differences do not impact safety or effectiveness.

Item	Subject Device	Primary Predicate	Equivalence
	HA*nano* InterFuse® Modular Interbody	**InterFuse® Intervertebral Body Fusion Device (K091988)**	
Device	Intervertebral Fusion Device with Bone Graft, Lumbar	Intervertebral Fusion Device with Bone Graft, Lumbar	Equivalent
Regulation Description	Intervertebral body fusion device	Intervertebral body fusion device	Equivalent
Regulation Number	21 CFR 888.3080	21 CFR 888.3080	Equivalent
Product Code	MAX	MAX	Equivalent
Material	PEEK per ASTM F2026 HA*nano* surface coating	PEEK per ASTM F2026	Substantially Equivalent
Manufacturing	Traditional Molding and Manufacturing Surface treatment with HA*nano*	Traditional Molding and Machining	Substantially Equivalent
Sterilization	Sterile	Sterile	Equivalent
Implantation Level	L2 to S1	L2 to S1	Equivalent

Performance Testing – Non-Clinical:
There are no changes to material or geometric design of the implant itself, so a full performance characterization of the device was deemed not necessary. Any changes in material strength that resulted from the surface coating are evaluated through the adhesion testing provided by the contract manufacturer, Promimic.

Performance Testing – Clinical:
Clinical testing was not applicable to support a substantial equivalence determination for the subject device.

Conclusion
Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.