September 17, 2024

Nvision Biomedical Technologies, Inc.
℅ Jeffrey Brittan
Vice President of Product Realization
Watershed Idea Foundry, Inc. (dba SpiTrex 3D)
1815 Aston Ave., STE 106
Carlsbad, California 92008

Re: K240250
Trade/Device Name: 3D Printed PEEK Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: August 16, 2024
Received: August 19, 2024

Dear Jeffrey Brittan:

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,

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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K240250

Device Name

3D Printed PEEK Interbody System

Indications for Use *(Describe)*

The 3D Printed PEEK Interbody System (ALIF) is intended for spinal fusion procedures in the lumbosacral spine at one or two contiguous levels from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral body fusion device. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). DDD patients may also have Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The device must be used with supplemental fixation and is intended for use with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. The device is to be implanted via an anterior approach.

The 3D Printed PEEK Interbody System (Cervical) is intended for spinal fusion procedures in the cervical spine at one or two contiguous levels from C2 to T1 in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). The device must be used with supplemental fixation and is intended for use with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. The device is to be implanted via an anterior approach.

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.**

# 510(k) Summary

**DATE PREPARED**
September 16, 2024

**CONTACT DETAILS**

**Applicant**
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San Antonio, TX 78249, USA
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Applicant Contact: Diana Langham, Director of Regulatory and Corporate Compliance

**Correspondent / Consultant**
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Watershed Idea Foundry, Inc. (dba SpiTrex 3D)
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**DEVICE NAME**

**Device Trade Name**
3D Printed PEEK Interbody System

**Common Name**
Intervertebral body fusion device

**Classification Name, Regulation Number & Product Code**
Intervertebral Fusion Device with Bone Graft, Lumbar
Intervertebral Fusion Device with Bone Graft, Cervical
Regulation: 21 CFR 888.3080
Product Code: MAX (lumbar), ODP (cervical)

**LEGALLY MARKETED PREDICATE DEVICES**
The subject device is substantially equivalent to the following predicates:

| *510(k) #* | *Manufacturer & Predicate Device Name* | *Predicate* |
|---|---|---|
| K193645 | Nvision Biomedical Technologies nva, nvp, and nvt (MAX) | Primary Predicate |
| K190380 | Nvision Biomedical Technologies nvc (ODP) | Additional Predicate |
| K213030 | Curiteva Porous PEEK Cervical Interbody Fusion System (ODP) | Additional Predicate |

**DEVICE DESCRIPTION SUMMARY**
The 3D Printed PEEK Interbody System devices are spinal fusion implants that are inserted into the intervertebral body space of the spine to act as disc spacers and hold bone graft. These devices are manufactured from PEEK OPTIMA™ LT1AMR5 with tantalum radiographic markers and are offered in multiple footprint, height, and lordotic angle options.

**INTENDED USE / INDICATIONS FOR USE**
The 3D Printed PEEK Interbody System (ALIF) is intended for spinal fusion procedures in the lumbosacral spine at one or two contiguous levels from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment prior to treatment with an intervertebral body fusion device. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). DDD patients may also have Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The device must be used with supplemental fixation and is intended for use with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. The device is to be implanted via an anterior approach.

The 3D Printed PEEK Interbody System (Cervical) is intended for spinal fusion procedures in the cervical spine at one or two contiguous levels from C2 to T1 in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). The device must be used with supplemental fixation and is intended for use with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. The device is to be implanted via an anterior approach.

**INDICATIONS FOR USE COMPARISON**
The subject device has the same intended use / indications for use as the predicates. Although phrasing may differ slightly, there are no significant differences between the subject device and predicates with respect to indications. The subject and predicate devices are equivalently indicated for spinal fusions using bone graft and supplemental fixation at the same spinal levels in the same patient populations.

**TECHNOLOGICAL COMPARISON**
The subject device has equivalent technological characteristics as the predicates. The subject devices are designed in the same sizes and geometries with equivalent features as the Nvision predicates but are 3D printed, which allows inclusion of porous latticed areas that provide additional surface for interfacing with bone. Inclusion of these porous features is equivalent to the Curiteva predicate, which is also 3D printed. The subject device ALIF also includes a porous central bridge feature that provides additional surface for device-tissue contact but does not change the function or performance of the device and maintains at least equivalent graft area for bony fusion.

**NON-CLINICAL TESTS SUMMARY & CONCLUSIONS**

Bench top mechanical testing was performed, which addresses recommendations from the FDA Class II Special Controls Guidance Document: Intervertebral Body Fusion Device.

- Static and dynamic torsion per ASTM F2077 (Cervical devices)
- Static and dynamic axial compression and compression shear per ASTM F2077 (Cervical and ALIF devices)
- Subsidence per ASTM F2267 (Cervical and ALIF devices)
- Expulsion testing (Cervical and ALIF devices)

Impaction testing per lab protocol was also performed (Cervical and ALIF devices).

Clinical testing was not applicable for this submission.

The non-clinical testing demonstrates that the subject devices have at least equivalent mechanical strength as the predicates and are as safe, as effective, and perform as well or better than these legally marketed devices.