April 28, 2022

Nvision Biomedical Technologies, Inc.
% Jeffrey Brittan
Vice President of Product Realization
Watershed Idea Foundry
1815 Aston Ave., Suite 106
Carlsbad, California 92008

Re: K212477
Trade/Device Name: EARP Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 30, 2022
Received: April 1, 2022

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 (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 L. 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)*
K212477

Device Name
EARP Interbody System

Indications for Use *(Describe)*

The EARP Interbody System is intended for intervertebral body fusion in the lumbar spine in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 of the lumbosacral spine. 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 cage. DDD patients may also have Grade 1 spondylolisthesis or retrolisthesis at involved levels. The device system must be used with supplemental fixation and autograft to facilitate fusion and is implanted via a posterolateral 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
April 27, 2022

MANUFACTURER
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PROPRIETARY NAME OF SUBJECT DEVICE
EARP Interbody System

COMMON NAME
Intervertebral Fusion Device with Bone Graft, Lumbar

DEVICE CLASSIFICATION
Intervertebral Body Fusion Device
(Classification Regulations: 21 CFR 888.3080, Product Codes: MAX, Class: II)

PREMARKET REVIEW
Orthopedic Devices, Spine Devices

INDICATIONS FOR USE
The EARP Interbody System is intended for intervertebral body fusion in the lumbar spine in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 of the lumbosacral spine. 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 cage. DDD patients may also have Grade 1 spondylolisthesis or retrolisthesis at involved levels. The device system must be used with supplemental fixation and autograft to facilitate fusion and is implanted via a posterolateral approach.

DEVICE DESCRIPTION
EARP implants are intervertebral body fusion devices used in the lumbar spine following discectomy. All devices are manufactured from PEEK Optima LT1 per ASTM F2026 and include tantalum markers per ASTM F560 for radiographic visualization. The devices have multiple footprints to adapt to the general shape of the vertebral endplates and have a hollow center to accommodate bone graft. Each footprint is available in multiple heights to accommodate patient variability and there are anti-migration features on the superior and inferior surfaces designed to improve fixation, stability, and prevent back out and migration.

PREDICATE DEVICE IDENTIFICATION
The subject EARP Interbody System is substantially equivalent to the following predicates:

510(k) Number	*Manufacturer & Predicate Device Name*	*Primary Predicate*
K193645	Nvision Biomedical's nv^{a}, nv^{p}, and nv^{t} system	✓

SUMMARY OF NON-CLINICAL TESTING
No FDA performance standards have been established for the EARP Interbody System. The following was performed to demonstrate equivalence of mechanical safety:

- Engineering analysis of mechanical performance in compression and compression-shear (ASTM F2077), subsidence (ASTM F2267), and expulsion.

The results of the engineering analysis demonstrated that the EARP Interbody System is substantially equivalent to the tested predicate devices.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS
The EARP Interbody System is substantially equivalent to the predicate devices. The subject implants maintain the same materials and features as the previously cleared devices but add a wider range of footprint sizes. These modifications do not change the intended use or performance of the device and do not raise additional questions of substantial equivalence. These technological characteristics have undergone engineering analysis to ensure the device would have equivalent performance as the predicates.

CONCLUSION
Based on the engineering analysis of device characteristics, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices. The equivalent indications for use, technological characteristics, and performance characteristics for the proposed EARP Interbody System are assessed to be substantially equivalent to the predicate devices.