January 13, 2020

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

Re: K193645
Trade/Device Name: nv^a, nv^p, and nv^t
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 27, 2019
Received: December 30, 2019

Dear Mr. 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 (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193645

Device Name
nv^a, nv^p, and nv^t

Indications for Use *(Describe)*

The nv^a, nv^p, and nv^t are 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 systems must be used with supplemental fixation and autograft to facilitate fusion and are implanted via an anterior, posterior, or transforaminal approach. Hyperlordotic interbody devices (>20° lordosis) must be used with at least anterior supplemental fixation or anterior buttress plate with posterior supplemental fixation.

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 6, 2020

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
nv^a, nv^p, and nv^t

COMMON NAME
Intervertebral Fusion Device with Bone Graft, Lumbar

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

PREMARKET REVIEW
Orthopedic Panel

INDICATIONS FOR USE
The nv^a, nv^p, and nv^t are 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 systems must be used with supplemental fixation and autograft to facilitate fusion and are implanted via an anterior, posterior, or transforaminal approach. Hyperlordotic interbody devices (>20° lordosis) must be used with at least anterior supplemental fixation or anterior buttress plate with posterior supplemental fixation.

DEVICE DESCRIPTION

The nv^a, nv^p, and nv^t are intervertebral body fusion devices used in the lumbar spine following discectomy. All devices are manufactured from PEEK Optima LT1 per ASTM F2026 or PEEK Optima HA Enhanced 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. The devices are implanted via a variety of approaches including anterior, posterior, or transforaminal. 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 nv^a, nv^p, and nv^t system is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K162426	Nvision Biomedical's nv^a, nv^p, and nv^t system	✓
K142594	Nvision Biomedical's nv^a, nv^p, and nv^t system	
K170855	Siats LLC's T-Rex Standalone ALIF	
K180502	Renovis Surgical Technologies, Inc's S128 ALIF System	

The following reference devices are also cited in this submission:

- Nvision Biomedical's Vector Hammertoe Correction System (K183055)
- Omnia Medical, LLC's Omnia Medical VBR (K172323)

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the nv^a, nv^p, and nv^t. The following was performed to demonstrate safety per methods of the previous submission:

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

The results of the engineering analysis indicate that the nv^a, nv^p and nv^t system is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the nv^a, nv^p and nv^t modifications are substantially equivalent to the predicate devices. The subject implants maintain the same features as the previously cleared devices but add a wider range of footprint size and lordotic angle options. The subject implants will continue to be manufactured from PEEK Optima LT1 but also add the option of PEEK Optima HA Enhanced. In addition, minor size/positioning adjustments to the nv^a implant mate holes further enhance surgeon ease of use following the same surgical technique. 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 is as safe and effective 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 similar indications for use, technological characteristics, and performance characteristics for the proposed nv^a, nv^p and nv^t options are assessed to be substantially equivalent to the predicate devices.