DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 29, 2016

Nvision Biomedical Technologies, LLC
% Allison Komiyama, Ph.D.
AcKnowledge Regulatory Strategies
2834 Hawthorn Street
San Diego, California 92104

Re: K162426
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: August 26, 2016
Received: August 30, 2016

Dear Dr. Komiyama:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162426

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K162426

DATE PREPARED
September 28, 2016

MANUFACTURER AND 510(k) OWNER
Nvision Biomedical Technologies, LLC
1350 N Loop 1604 E, Suite 103, San Antonio, TX 78232, USA
Telephone: (210) 545-3713
Fax: (866) 764-1139
Official Contact: Diana L. Langham, Director of Regulatory and Corporate Compliance

REPRESENTATIVE/CONSULTANT
Allison C. Komiyama, Ph.D., R.A.C.
AcKnowledge Regulatory Strategies
Telephone: +1 (619) 208-7888
Email: akomiyama@acknowledge-rs.com

PROPRIETARY NAME OF SUBJECT DEVICE
nv^a, nv^p, and nv^t

COMMON NAME
Intervertebral Fusion Device with Bone Graft, Lumbar

DEVICE CLASSIFICATION
Intervertebral body fusion device
(21 CFR 888.3080, Product Code MAX, Class II)

PREMARKET REVIEW
ODE/DOD/ASDB
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.

510(k) Summary

DEVICE DESCRIPTION

The nv^a, nv^p, and nv^t are an intervertebral body fusion device 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 purpose of this submission is to make changes to the number and design of the tantalum markers.

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 nv^a, nv^p, and nv^t is substantially equivalent to the nv^a, nv^p, and nv^t device by Nvision Biomedical Technologies, LLC, cleared in K142594. K142594 is the primary predicate.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the nv^a, nv^p, and nv^t. A summary of the following tests that were performed was provided in order to demonstrate safety based on current industry standards:

- Static and dynamic compression (per ASTM F2077)
- Subsidence (per ASTM F2267)
- Expulsion

The results of these tests indication that the nv^a, nv^p, and nv^t is substantially equivalent to the predicate devices.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Nvision believes that the nv^a, nv^p, and nv^t is substantially equivalent to the predicate devices based on the information summarized here:
The subject device has identical dimensions, the same indications for use, and uses the same materials as the devices cleared in K142594. The subject device has a similar design and similar technological characteristics to the devices cleared in K142594. The device uses the same instrumentation as those cleared in K142594.

CONCLUSION

The nv^a, nv^p, and nv^t is considered substantially equivalent to the predicate devices based on the design control activities provided in the submission. Based on the summary of the testing that was performed, the identical indications for use, and similar technological characteristics, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices.