March 21, 2019

Nvision Biomedical Technologies, Inc.
% Mr. Jeffrey Brittan
Consultant
Watershed Ideas Foundry
1815 Aston Ave., Suite 106
Carlsbad, California 92008

Re: K190380
  Trade/Device Name: nv
  Regulation Number: 21 CFR 888.3080
  Regulation Name: Intervertebral Body Fusion Device
  Regulatory Class: Class II
  Product Code: ODP
  Dated: February 18, 2019
  Received: February 19, 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
<table>
<thead>
<tr>
<th>510(k) Number (if known)</th>
<th>K190380</th>
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<tbody>
<tr>
<td>Device Name</td>
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### Indications for Use

The nvc is intended for spinal fusion procedures at one level, from C2-T1, in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. One device is to be used per intervertebral space. Patients should receive six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The nvc devices must be used with supplemental fixation and are designed for use with autograft bone to facilitate fusion. The devices are to be implanted via an anterior approach.
510(k) Summary

DATE PREPARED
February 4, 2018

MANUFACTURER AND 510(k) OWNER
Nvision Biomedical Technologies, Inc.
4754 Shavano Oak, Suite 101
San Antonio, TX 78249, USA
Telephone:  (210) 545-3713
Fax:             (866) 764-1139
Official Contact: Diana Langham, Director of Regulatory and Corporate Compliance

REPRESENTATIVE/CONSULTANT
Jeffrey Brittan
Watershed Ideas Foundry
Telephone:  (714) 287-6780
Email: jeffbrittan@watershedideas.com

PROPRIETARY NAME OF SUBJECT DEVICE
nv

COMMON NAME
Intervertebral Fusion Device with Bone Graft, Cervical

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

PREMARKET REVIEW
Orthopedic Panel

INDICATIONS FOR USE
The nv is intended for spinal fusion procedures at one level, from C2-T1, in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. One device is to be used per intervertebral space. Patients should receive six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The nv devices must be used with supplemental fixation and are designed for use with autograft bone to facilitate fusion. The devices are to be implanted via an anterior approach.
DEVICE DESCRIPTION
The nvc is an intervertebral body fusion device used in the cervical 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. The devices are implanted via an anterior approach. 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 nvc device is substantially equivalent to the previously cleared nvc devices by Nvision Biomedical Technologies, Inc.

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<tr>
<th>510(k) Number</th>
<th>Predicate Device Name / Manufacturer</th>
<th>Primary Predicate</th>
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<tbody>
<tr>
<td>K170074</td>
<td>nvc from Nvision Biomedical Technologies</td>
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<tr>
<td>K142328</td>
<td>nvc from Nvision Biomedical Technologies</td>
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SUMMARY OF NON-CLINICAL TESTING
No FDA performance standards have been established for the nvc System. The following was performed to demonstrate safety based on recognized consensus standards and current industry practice:

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

The results of the engineering analysis indicate that the nvc system is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES
Nvision believes that the nvc system is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same indications for use, utilizes identical materials and processing, and incorporates equivalent design features and technical characteristics as the devices cleared in K170074. The implant utilizes the same instrumentation as that cleared in the predicate system and is offered in the same heights and lordotic angles; the added footprint size does not change the intended use or performance of the device and does 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
The nv^c is considered substantially equivalent to the predicate devices based on the design control activities provided in the submission. Based on the summary of the analysis 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.