July 5, 2023

Nvision Biomedical Technologies, Inc
Analaura Villarreal-Berain
Extremity Project Engineer
4590 Lockhill Selma
San Antonio, Texas 78249

Re: K222015
Trade/Device Name: Integral Titanium Cervical Interbody
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: May 31, 2023
Received: June 5, 2023

Dear Analaura Villarreal-Berain:

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,

Katherine D. Kavlock -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K222015

Device Name
Integral Titanium Cervical Interbody

Indications for Use *(Describe)*

The Integral Titanium Cervical Interbody 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 back 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 Integral Titanium Cervical Interbody 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.

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.

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

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510(k) Summary

DATE PREPARED
June 21, 2023

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
Integral Titanium Cervical Interbody

COMMON NAME
Cervical Intervertebral Body Fusion Device

DEVICE CLASSIFICATION
Intervertebral Body Fusion Device with Bone Graft, Cervical
(21 CFR 888.3080, Product Code ODP, Class II)

INDICATIONS FOR USE
The Integral Titanium Cervical Interbody 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 back 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 Integral Titanium Cervical Interbody 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 Integral Titanium Cervical Interbody is an intervertebral body fusion device used in the cervical spine following discectomy. All devices are additively manufactured using titanium alloy per ASTM F3001.

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 (ACIF) surgical 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.

PREDICATE DEVICE IDENTIFICATION
The Integral Titanium Cervical Interbody is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate*
K190380	Nvision Biomedical Technologies nv^{c} System	Primary
K171140	Nexxt Spine Matrixx System	Additional
K203342	Orthofix CONSTRUX Mini Ti Spacer System	Additional

The following reference devices are also cited in this submission:

- Nvision Biomedical's Quantum Cervical Plate (K210424)

SUMMARY OF NON-CLINICAL TESTING
No FDA performance standards have been established for the Integral Titanium Cervical Interbody. The following tests were performed to demonstrate safety based on recognized consensus standards and current industry practice:

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

The results of these tests, as well as engineering analysis of device characteristics, indicate that the Integral Titanium Cervical Interbody is substantially equivalent to the predicate devices.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS
Nvision believes that the Integral Titanium Cervical Interbody is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design, similar dimensions, and uses similar or identical materials as the devices cleared in K190380, K171140 and K203342. The subject device also has the same intended use, as well as similar technological characteristics (graft windows, insertion features) as these predicates. The Indications for Use are equivalent and any minor differences in wording choices are insignificant. These technological characteristics have undergone testing and engineering analysis to ensure the device is as safe and effective as the predicates.

CONCLUSION
Based on the testing performed, including static compression, dynamic compression, static torsion, dynamic torsion, subsidence, expulsion as well as 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 Integral Titanium Cervical Interbody are assessed to be substantially equivalent to the predicate devices.