October 22, 2021

Analaura Villarreal-Berain
Extremity Project Engineer
4590 Lockhill Selma
San Antonio, Texas 78249

Re: K210424
Trade/Device Name: Quantum Anterior Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 9, 2021
Received: February 11, 2021

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

801and Part 809); 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,

Colin O'Neill, M.B.E.
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)*

Device Name
Quantum Anterior Cervical Plate

K210424

Indications for Use *(Describe)*
The Quantum Anterior Cervical Plate is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

•degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
• spondylolisthesis,
• trauma (i.e. fractures or dislocations),
• tumors,
• deformity (defined as kyphosis, lordosis, or scoliosis),
• pseudarthrosis,
• failed previous fusion,
• spinal stenosis.

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
February 9, 2021

MANUFACTURER AND 510(k) OWNER
Nvision Biomedical Technologies, Inc.
4590 Lockhill Selma
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
Analaura Villarreal-Berain, Extremity Project Engineer
Nvision Biomedical Technologies
Telephone: (210) 545-3713 ext. 109
Email: analauravillarreal@nvisionbiomed.com

PROPRIETARY NAME OF SUBJECT DEVICE
Quantum Anterior Cervical Plate

COMMON NAME
Anterior Cervical Plate

DEVICE CLASSIFICATION
Spinal intervertebral body fixation orthosis
(21 CFR 888.3060, Product Code KWQ, Class II)

PREMARKET REVIEW
ODE/DOD/ASDB
Orthopedic Panel

INDICATIONS FOR USE
The Quantum Anterior Cervical Plate is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:
• degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
• spondylolisthesis,
• trauma (i.e. fractures or dislocations),
• tumors,
• deformity (defined as kyphosis, lordosis, or scoliosis),
• pseudarthrosis,

• failed previous fusion,
• spinal stenosis.

DEVICE DESCRIPTION
The Quantum Anterior Cervical Plate is a titanium alloy plate, conforming to ASTM F3001, intended for anterior screw fixation of the plate to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-drilling and self-tapping bone screws using an anterior approach. Plates are available in a variety of lengths (08 mm – 110 mm), addressing multiple levels of fixation (one to five). The plate incorporates graft visualization holes on the longitudinal center line for intraoperative visualization. Bone screws are available in three diameters (3.75 mm, 4.25 mm, and 4.75 mm) and a variety of lengths (10 mm – 20 mm). Screws are made from titanium alloy per ASTM F136.

PREDICATE DEVICE IDENTIFICATION
The Quantum Anterior Cervical Plate is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K161524	Tangis Anterior Cervical Plate / Nvision Biomedical Technologies	✓
K151553	Anterior Cervical Plate System / Osteomed Implantes, LTDA	
K031276	ACLP System / Synthes Spine	

The following reference devices are also cited in this submission:
- Nvision Biomedical's Multi-Drive Interference Screw System (K200428)

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

• Static and dynamic compression (per ASTM F1717)
• Static torsion (per ASTM F1717)

The results of these tests, as well as engineering analysis of device characteristics, indicate that the Quantum Anterior Cervical Plate is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES
Nvision believes that the Quantum Anterior Cervical Plate 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 K161524, K151553 and K031276. The subject device also has

the same intended use, as well as similar technological characteristics (variable and fixed screws, screw locking 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 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 Quantum Anterior Cervical Plate are assessed to be substantially equivalent to the predicate devices.