December 6, 2017

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

Re: K173091
Trade/Device Name: Boundary Anterior Lumbar Buttress Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 28, 2017
Received: September 29, 2017

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 Part 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Ronald P. Jean -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)*

K173091

Device Name
Boundary Anterior Lumbar Buttress Plate

Indications for Use *(Describe)*

The Boundary Anterior Lumbar Buttress Plate is intended to stabilize the allograft or autograft at one level (L1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

DATE PREPARED
September 28, 2017

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

REPRESENTATIVE/CONSULTANT
Allison C. Komiyama, Ph.D., R.A.C.
Lucie Dalet, Ph.D.
AcKnowledge Regulatory Strategies, LLC
Telephone: +1 (619) 738-8646
Email: akomiyama@acknowledge-rs.com

PROPRIETARY NAME OF SUBJECT DEVICE
Boundary Anterior Lumbar Buttress Plate

COMMON NAME
Appliance, Fixation, Spinal Intervertebral Body

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 Boundary Anterior Lumbar Buttress Plate is intended to stabilize the allograft or autograft at one level (L1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials. This device is not intended for load bearing applications.

DEVICE DESCRIPTION

The Boundary Anterior Lumbar Buttress Plate is a fixation system used as a buttress of the interbody, to stabilize the allograft or autograft at one level during the development of a spinal fusion. The device consists in a plate shaped to conform to the anatomy of the anterior lumbar and lumbosacral spine (L1-S1). A screw fixates the system to the anterior surface of the vertebral body, allowing the plate to extend onto the adjacent intervertebral space. The buttress end of the plate may be oriented either caudal or cephalad. The Boundary Anterior Lumbar Buttress Plate may be used alone or with other anterior, anterolateral, or posterior spinal systems made of compatible materials.

PREDICATE DEVICE IDENTIFICATION

The Boundary Anterior Lumbar Buttress Plate is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K092659	RCS® Anterior Buttress Plate System / Precision Spine, Inc.	✓
K133911	Anterior Buttress Plate System / Genesys Spine	
K161524	Tangis Anterior Cervical Plate / Nvision Biomedical Technologies,LLC	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Boundary Anterior Lumbar Buttress Plate. The following tests were performed to demonstrate safety based on current industry standards:

- Static Cantilever Bending per ASTM F1717-13
- Dynamic Cantilever Bending per ASTM F1717-13

The results of these tests indicate that the Boundary Anterior Lumbar Buttress Plate is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the Boundary Anterior Lumbar Buttress Plate is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and dimension as the devices cleared in K092659 and K133911. The subject device uses similar or identical materials as the devices cleared in K092659, K133911, and K161524. The subject device has similar intended use and similar technological characteristics (self-tapping and self-drilling screws) as the devices cleared in K092659 and K133911. These technological characteristics have undergone testing to ensure the device is as safe and effective as the predicates.

CONCLUSION

Based on the testing performed, including static and dynamic cantilever bending, 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 Boundary Anterior Lumbar Buttress Plate are assessed to be substantially equivalent to the predicate devices. The device is considered safe and effective for its intended use.