Nvision Biomedical Technologies, LLC
% Allison Komiyama, Ph.D.
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2934 Hawthorn Street
San Diego, California 92104

Re: K180458
Trade/Device Name: FOCUS Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw Systems
Regulatory Class: Class II
Product Code: NKB
Dated: February 16, 2018
Received: February 20, 2018

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,

Colin O'neill -S
for MNM

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180458

Device Name
FOCUS Pedicle Screw System

Indications for Use *(Describe)*
The FOCUS Pedicle Screw System is intended for use in the non-cervical posterior spine (T1 to S1) to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), spinal stenosis, tumor, pseudarthrosis, and failed previous fusion.

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.

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510(k) Summary
K180458

DATE PREPARED
April 16, 2018

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PROPRIETARY NAME OF SUBJECT DEVICE
FOCUS Pedicle Screw System

COMMON NAME
Thoracolumbosacral Pedicle Screw System

DEVICE CLASSIFICATION
Thoracolumbosacral Pedicle Screw System
(21 CFR 888.3070, Product Code NKB, Class II)

PREMARKET REVIEW
ODE/DOD/PSDB
Orthopedic

INDICATIONS FOR USE
The FOCUS Pedicle Screw System is intended for use in the non-cervical posterior spine (T1 to S1) to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), spinal stenosis, tumor, pseudarthrosis, and failed previous fusion.

510(k) Summary

DEVICE DESCRIPTION

The FOCUS Pedicle Screw System is a spinal system used as an adjunct to fusion, to provide immobilization and stabilization of spinal segments in the non-cervical posterior spine (T1 to S1) of skeletally mature patients. The system consists in pedicle screws implanted into the bones, and capturing spinal rods. The system is stabilized by cross connectors. The device is implanted via a posterior approach.

PREDICATE DEVICE IDENTIFICATION

The FOCUS Pedicle Screw System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K161363	Arsenal Spinal Fixation System / Alphatec Spine, Inc.	✓
K101278	Inertia Pedicle Screw System / Nexxt Spine LLC	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the FOCUS Pedicle Screw System. The following tests were performed to demonstrate safety based on current industry standards:

- Static compression bending (per ASTM F1717)
- Dynamic compression bending (per ASTM F1717)
- Static torsion (per ASTM F1717)
- Axial pullout (per ASTM F543)

The results of these tests indicate that the FOCUS Pedicle Screw System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the FOCUS Pedicle Screw System 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 K101278 and K161363. The subject device has the same intended use as the device cleared in K161363, except that the subject device is not intended to be used in pediatric population. The subject device has similar technological characteristics (polyaxial, cannulated, cortical, self-tapping screws, straight or pre-contoured rods) as the devices cleared in K161363 and K101278. 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 compression bending, dynamic compression bending, static torsion, and axial pullout, 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 FOCUS Pedicle Screw System are assessed to be substantially equivalent to the predicate devices.