February 19, 2019

Nvision Biomedical Technologies, LLC
% Jeffrey Brittan
Consultant
Watershed Ideas Foundry
1815 Aston Avenue, Suite 106
Carlsbad, California 92008

Re: K183055
Trade/Device Name: VECTOR Hammertoe Correction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 17, 2019
Received: January 18, 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,

Laurence D. Coyne -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183055

Device Name

VECTOR Hammertoe Correction System

Indications for Use *(Describe)*

The Vector Hammertoe Correction System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

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 7, 2019

MANUFACTURER AND 510(k) OWNER
Nvision Biomedical Technologies, LLC
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
VECTOR™ Hammertoe Correction System

COMMON NAME
Bone Fixation Screw

DEVICE CLASSIFICATION
Smooth or Threaded Metallic Bone Fixation Fastener
(Classification Regulations: 21 CFR 888.3040, Product Codes: HWC, Class: II)

PREMARKET REVIEW
ODE/DOD/Joint and Fixation Devices (JFDB2)
Orthopedic Panel

INDICATIONS FOR USE
The Vector Hammertoe Correction System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe.

DEVICE DESCRIPTION
The VECTOR Hammertoe Correction System is comprised of a sterile PEEK (polyetheretherketone) HA (hydroxyapatite) fixation device. The implants are offered in Ø3.50mm and Ø4.00mm and in 0° angle. The system has K-wires, drill, taps, implant inserters, and sizers manufactured from medical grade stainless steel.

PREDICATE DEVICE IDENTIFICATION
The Vector Hammertoe Correction System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*
K133636	Extremity Medical HammerFIX Device* (primary)
K112675	Arrowhead Medical Arrow-Lok Digital System** (secondary)

*Additional HammerFIX clearances include K152710
**Additional Arrow-Lok clearances include K100926

The following reference devices are also cited:

510(k) Number	*Reference Device Name / Manufacturer*
K151785	Innovasis Px HA PEEK IBF System
K162426	Nvision Nva, Nvp, and Nvt Systems

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

- Torsion, driving torque, and axial pullout (per ASTM F543), as well as static and dynamic bending
- The device has been tested (LAL testing) to meet recommended Bacterial Endotoxins limits of 20 EU/device.

The results of these tests, as well as engineering analysis of device characteristics, indicate that the VECTOR Hammertoe Correction System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES
Nvision believes that the Vector Hammertoe Correction System is substantially equivalent to the predicate devices based on the information summarized here.

The subject device system has a similar design, similar dimensions, and uses similar or identical materials as the devices cleared K133636, K112675, K151785, and K162426. The subject device also has the same intended use, as well as similar technological characteristics as these predicates (orthopedic fixation implants in a range of sizes). The Indications for Use for the predicates are equivalent and these technological characteristics have undergone testing and engineering analysis to ensure the subject system is as safe and effective as the predicates.

Bone fixation is the technological principle for both the subject and predicate devices. It is based on use of an implant for the fixation of osteotomies and reconstruction of the lesser toe following correction procedures for hammertoe, claw toe, and mallet toe. At a high level, subject and primary predicate device equivalence is based on the following same technical elements:

- Screw and barbed segments for fixation to bone
- Cannulation that accommodates use over a k-wire
- Use of an insertion instrument for delivery

The following technological differences exist between the subject and primary predicate device:

- Inclusion of a marker for radiographic visualization
- The subject device is manufactured from PEEK HA, whereas the predicate device is PEEK

CONCLUSION

Based on the testing performed, including torsion, driving torque, pullout, and static and dynamic bending, 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 Vector Hammertoe Correction System are assessed to be substantially equivalent to the predicate devices.