February 25, 2020

Nvision Biomedical Technologies, Inc.
℅ Jeffrey Brittan
Vice President of Product Realization
Watershed Idea Foundry
1815 Aston Ave., Suite 106
Carlsbad, California 92008

Re: K193414
Trade/Device Name: Trigon HA Stand-Alone Wedge Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PLF, HWC
Dated: December 6, 2019
Received: December 9, 2019

Dear Jeffrey 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/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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K193414

Device Name
Trigon HA Stand-Alone Wedge Fixation System

Indications for Use *(Describe)*

The Trigon™ HA Stand-Alone Wedge Fixation System is intended to be used for internal bone fixation for bone fractures or osteotomies in the foot, such as:

- Cotton (opening wedge) osteotomies of the medial cuneiform
- Evans lengthening osteotomies

The Trigon Ti wedges are intended for use with ancillary fixation.

The Trigon Ti Stand-Alone Wedge Fixation System is not intended for use in the spine.

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

DATE PREPARED
February 6, 2020

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
Trigon™ HA Stand-Alone Wedge Fixation System

COMMON NAME
Bone Wedge

DEVICE CLASSIFICATION
Single/multiple component metallic bone fixation appliances and accessories
(Classification Regulations: 21 CFR 888.3030, Product Codes: PLF, HWC, HRS, Class: II)

PREMARKET REVIEW
Orthopedic Device Panel

INDICATIONS FOR USE
The Trigon HA Stand-Alone Wedge Fixation System is intended to be used for internal bone fixation for bone fractures or osteotomies in the foot, such as:

- Cotton (opening wedge) osteotomies of the medial cuneiform
- Evans lengthening osteotomies

The Trigon Ti wedges are intended for use with ancillary fixation.

The Trigon Ti Stand-Alone Wedge Fixation System is not intended for use in the spine.

DEVICE DESCRIPTION

The Trigon HA Stand-Alone Wedge Fixation System is a family of PEEK Optima HA Enhanced (HA PEEK) wedges with tantalum markers used for angular correction of small bones of the foot. The wedges incorporate two screw-receiving holes, surface teeth, and an area to contain grafting material. The wedges are designed in rectangular and kidney shaped footprints in a range of sizes (16x16mm to 20x22mm) and in multiple thicknesses (5 to 12mm). The associated 2.5mm diameter titanium screws are designed in lengths of 10 to 30mm.

When used with the provided screw fixation the Trigon wedges may be used with or without ancillary plating. When used without the provided screws Trigon wedges are intended for use with ancillary fixation.

PREDICATE DEVICE IDENTIFICATION

The Trigon HA Stand-Alone Wedge Fixation System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K161037	Life Spine Tarsa-Link Wedge Fixation System	✓
K140531	Wright Medical Technology BIOFOAM Bone Wedge	
K151256	Arthrex BioSync Wedge System	
K192645	Nvision Trigon Ti Stand-Alone Wedge Fixation System	

The following reference devices are also cited in this submission:

- Nvision Biomedical's Vector Hammertoe Correction System (K183055)
- Nvision Biomedical's Healix Compression Screw System (K182949)
- Siats LLC's T-Rex Standalone ALIF (K170855)

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Trigon HA Stand-Alone Wedge Fixation System. The following testing was performed:

- Compression (per ASTM F2077)
- Expulsion
- Engineering analysis to evaluate screw mechanical strength and pullout strength

The results of these tests indicate that the Trigon HA Stand-Alone Wedge Fixation System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the Trigon HA Stand-Alone Wedge Fixation System is substantially equivalent to the predicate devices. The subject wedges are similar to the predicates in that the footprint sizes and thicknesses are similar, they are intended for use with ancillary fixation, and they incorporate the same number of ancillary screws. Furthermore, the ancillary screws are similar in size. Trigon wedges are manufactured from HA PEEK while the primary predicate is manufactured from standard PEEK, however testing, analysis, and comparison to reference devices also manufactured from HA PEEK demonstrated that this does not negatively impact equivalence.

CONCLUSION

Based on the testing performed, including compression, expulsion, and engineering analysis, 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 Trigon HA Stand-Alone Wedge Fixation System are assessed to be substantially equivalent to the predicate devices.