November 8, 2024

Nvision Biomedical Technologies
Natalia Reyes
Senior Design Engineer
4590 Lockhill Selma
San Antonio, Texas 78249

Re: K243231
Trade/Device Name: Trigon PEEK HA Wedges
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, HRS
Dated: October 8, 2024
Received: October 9, 2024

Dear Natalia Reyes:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243231

Device Name

Trigon PEEK HA Wedges

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 ankle and foot, such as:

- Cotton (opening wedge) Osteotomies of the Medial Cuneiform
- Evans Lengthening Osteotomies
- Subtalar Arthrodesis
- First Metatarsal-Cuneiform Lengthening Arthrodesis
- Calcaneocuboid Arthrodesis
- Calcaneal Z Lengthening Osteotomies
- MTP Lengthening Arthrodesis
- Lesser Metatarsal-Cuneiform Lengthening Arthrodesis
- Navicular-Cuneiform Arthrodesis
- Talonavicular Arthrodesis

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

The Trigon HA 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K243231
510(k) Summary

DATE PREPARED
October 1, 2024

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

COMMON NAME
- Primary Bone Wedge
- Screw, Fixation, Bone
- Plate, Fixation, Bone

DEVICE CLASSIFICATION

Device	Product Code	Classification Regulation	Class
Primary Bone Wedge	Primary PLF	Primary 21 CFR 888.3030 Single/multiple components metallic bone fixation appliances and accessories	II
Bone Screw	HWC	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener	II
Bone Plate	HRS	21 CFR 888.3030 Single/multiple components metallic bone fixation appliances and accessories	II

PREMARKET REVIEW
Orthopedic Devices

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 ankle and foot, such as:

- Cotton (opening wedge) Osteotomies of the Medial Cuneiform
- Evans Lengthening Osteotomies
- Subtalar Fusion
- First Metatarsal-Cuneiform Lengthening Arthrodesis
- Calcaneocuboid Arthrodesis
- Calcaneal Z Lengthening Osteotomies
- MTP Lengthening Arthrodesis
- Lesser Metatarsal-Cuneiform Lengthening Arthrodesis
- Navicular-Cuneiform Arthrodesis
- Talonavicular Arthrodesis

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

The Trigon HA 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 an inserter-receiving hole and/or two screw-receiving holes and an area to contain grafting material. The wedges are designed in rectangular, kidney, circular, oval, and teardrop shaped footprints in a range of sizes and in multiple thicknesses. 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. Lapidus, Calcaneocuboid, MTP, Lesser Metatarsal, and Midfoot Wedges require additional fixation not provided in the Trigon System. When used without the provided screws, Trigon wedges are intended for use with ancillary fixation.

PREDICATE DEVICE IDENTIFICATION

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

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate*
K220197	Nvision Biomedical's Trigon™ HA Stand-Alone Wedge Fixation System	Primary
K193414	Nvision Biomedical's Trigon™ HA Stand-Alone Wedge Fixation System	Additional

Nvision Biomedical's nva, nvp, nvt (K193645) is also cited in this submission as a reference predicate device.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Trigon HA Stand-Alone Wedge Fixation System. The following was performed to demonstrate safety per methods of the previous submission:

- Engineering analysis comparing device characteristics including materials, intended use and processes (cleaning and sterilization methods)

The results of this comparison 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 modification is substantially equivalent to the predicate devices. The subject implants maintain the same features as the previously cleared devices with the addition of configurations for different foot procedures commonly performed. This modification does not change the intended use or performance of the device and does not raise additional questions of substantial equivalence. These technological characteristics have undergone a comparison of characteristics to ensure the device is as safe and effective as the predicates.

CONCLUSION

Based on the comparison 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 Trigon HA Stand-Alone Wedge Fixation System options are assessed to be substantially equivalent to the predicate devices.