December 1, 2022

Nvision Biomedical Technologies, Inc.
℅ Analaura Villarreal-Berain
Extremity Project Engineer
Nvision Biomedical Technologies, Inc
4590 Lockhill Selma
San Antonio, Texas 78249

Re: K223226
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: October 12, 2022
Received: October 18, 2022

Dear Analaura Villarreal-Berain:

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 -S

Shumaya Ali, M.P.H.
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)*

K223226

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 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

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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# K223226
# 510(k) Summary

**DATE PREPARED**
December 1, 2022

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

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

**DEVICE CLASSIFICATION**

| Device | Product Code | Classification Regulation | Class |
|---|---|---|---|
| Primary Bone Wedge | Primary PLF | Primary 21 CFR 888.3030<br>Single/multiple components metallic bone fixation appliances and accessories | II |
| Bone Screw | HWC | 21 CFR 888.3040<br>Smooth or threaded metallic bone fixation fastener | 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 arthrodesis
- Calcaneocuboid 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 two screw-receiving holes, surface teeth, 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, except for the Lapidus and Calcaneocuboid Wedges which will require ancillary 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 |
| K203445 | Nvision Biomedical's Trigon™ HA Stand-Alone Wedge Fixation System | Additional |
| 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 – Calcaneocuboid Wedge is substantially equivalent to the predicate devices.

**EQUIVALENCE TO PREDICATE DEVICES**

Nvision believes that the Trigon HA Stand-Alone Wedge Fixation System modification (addition of Calcaneocuboid Wedge) is substantially equivalent to the predicate devices. The subject implants maintain the same features as the previously cleared devices with an 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 – Calcaneocuboid Wedge options are assessed to be substantially equivalent to the predicate devices.