December 14, 2020

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

Re: K202657
Trade/Device Name: Javelin Tailor's Bunion 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: HRS, HWC
Dated: September 10, 2020
Received: September 14, 2020

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, 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)*

K202657

Device Name
Javelin Tailor's Bunion Fixation System

Indications for Use *(Describe)*

The Javelin Tailor's Bunion Fixation System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the foot (such as 5th metatarsal osteotomies for the correction of Tailor's Bunion). The system may be used in both adults and adolescent (13-21 years of age) patients.

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
September 10, 2020

MANUFACTURER AND 510(k) OWNER
Nvision Biomedical Technologies, Inc.
4590 Lockhill Selma
San Antonio, TX 78249, USA
Telephone: (210) 545-3713
Fax: (866) 764-1139
Official Contact: Diana Langham, Director of Regulatory and Corporate Compliance

REPRESENTATIVE
Analaura Villarreal Berain, Extremity Project Engineer
Nvision Biomedical Technologies
Telephone: (210) 545-3713 ext. 109
Email: analauravillarreal@nvisionbiomed.com

PROPRIETARY NAME OF SUBJECT DEVICE
Javelin™ Tailor's Bunion Fixation System

COMMON NAME
Plate, Fixation, Bone (primary)
Screw, Fixation, Bone

DEVICE CLASSIFICATION
Product Codes: HRS (Primary), HWC
Classification Regulations: 21 CFR 888.3030 (Primary): Single/multiple component metallic bone fixation appliances and accessories, 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener; Class II

PREMARKET REVIEW
Orthopedic Device Panel

INDICATIONS FOR USE
The Javelin Tailor's Bunion Fixation System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the foot (such as 5th metatarsal osteotomies for the correction of Tailor's Bunion). The system may be used in both adults and adolescent (13-21 years of age) patients.

DEVICE DESCRIPTION
The Javelin Tailor's Bunion Fixation System is a single-use bone fixation device intended to be permanently implanted. The system consists of a titanium alloy plate and screws that provide fixation for the 5th metatarsal. The plate has 4 screw-receiving holes and is designed to allow for intramedullary insertion and fixation at the proximal end. The associated 2.0mm to 3.0mm diameter titanium screws, locking and non-locking, are designed in lengths of 6 to 16mm. The system is provided non-sterile.

PREDICATE DEVICE IDENTIFICATION

The Javelin Tailor's Bunion Fixation System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	
K152312	Normed* RECON System – V-TEK-IVP Plates and Screws	Primary Predicate
K190365	Paragon 28 Inc. Baby Gorilla/Gorilla Plating System	Additional Predicate
K172148	Stryker Anchorage Bone Plating System	Additional Predicate
K182949	Nvision Biomedical's Healix Compression Screw System	Additional Predicate
K161524	Nvision Biomedical's Tangis Anterior Cervical Plate	Additional Predicate

* Subsequently acquired by Zimmer Inc.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Javelin Tailor's Bunion Fixation System. The following testing was performed:

- Static and dynamic bending (per ASTM F382)
- Axial pull-out (per ASTM F543)
- Engineering analysis to evaluate screw mechanical strength

The results of these tests indicate that the Javelin Tailor's Bunion Fixation System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the Javelin Tailor's Bunion Fixation System is substantially equivalent to the predicate devices. The subject plates are similar to the predicates in that the geometry, thicknesses and lengths are similar, they are intended for use with ancillary screws, and they incorporate the same number of ancillary screws. Furthermore, the ancillary screws are similar in size. The implants from the Javelin Tailor's Bunion Fixation System are manufactured using Titanium Alloy and the instruments using medical grade Stainless Steel, similar to the predicate.

CONCLUSION

Based on the testing performed, including static and dynamic bending, pull-out, 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 Javelin Tailor's Bunion Fixation System are assessed to be substantially equivalent to the predicate devices.