November 10, 2020

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

Re: K200428
Trade/Device Name: Multi-Drive Interference Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 14, 2020
Received: October 15, 2020

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/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,

Laura C. Rose, Ph.D.
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)*
K200428

Device Name
Multi-Drive Interference Screw System

Indications for Use *(Describe)*

The Multi-Drive Interference Screw System is intended for soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue and tendon transfers in surgeries of the shoulder, elbow, knee, foot/ankle, and hand /wrist. Specifically:

Shoulder:
Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle:
Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus Transfer for Achilles Tendon Reconstruction, and Flexor Digitorum Longus Transfer for Posterior Tibial Tendon Reconstruction

Knee:
Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis

Elbow:
Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist:
Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs. Ligament Reconstruction and Tendon Interposition

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) Number: K200428
Date Received: 02/24/2020

510(k) Summary

DATE PREPARED
October 22, 2020

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
Multi-Drive Interference Screw System

COMMON NAME
Interference Screw (fastener, fixation, nondegradable, soft tissue)

DEVICE CLASSIFICATION
Smooth or threaded metallic bone fixation fastener
(Classification Regulations: 21 CFR 888.3040, Product Code: MBI, Class: II)

PREMARKET REVIEW
Orthopedic Devices

INDICATIONS FOR USE
The Multi-Drive Interference Screw System is intended for soft tissue reattachment, i.e. fixation of ligament and tendon graft tissue and tendon transfers in surgeries of the shoulder, elbow, knee, foot/ankle, and hand /wrist. Specifically:

Shoulder:
Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle:
Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus

Transfer for Achilles Tendon Reconstruction, and Flexor Digitorum Longus Transfer for Posterior Tibial Tendon Reconstruction

Knee:
Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis

Elbow:
Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist:
Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs. Ligament Reconstruction and Tendon Interposition

DEVICE DESCRIPTION
The Multi-Drive Interference Screw System is a family of interference screws for the reattachment and fixation of tissue in surgeries of the shoulder, elbow, knee, foot/ankle, and hand /wrist. The interference screws are manufactured from HA Enhanced PEEK or titanium alloy in multiple lengths and diameters with key features including a threaded shank, cannulation hole, and multiple drive mating interface. The HA PEEK versions also incorporate tantalum pins for imaging visibility.

PREDICATE DEVICE IDENTIFICATION
The Multi-Drive Interference Screw System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name & Manufacturer*	*Primary Predicate*
K183690	Paragon 28's Tenodesis Screw System	✓
K180573	Responsive Arthroscopy's Interference Screw System	
K170877	Parcus Medical's SLiK Fix Interference Screw	

The following reference devices are also cited in this submission:

- Nvision Biomedical's Vector Hammertoe Correction System (K183055)
- Nvision Biomedical's Trigon™ Ti Stand-Alone Wedge Fixation System (K192645)
- Nvision Biomedical's Healix Compression Screw System (K182949)

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Multi-Drive Interference Screw System. The following testing was performed:

- Mechanical testing in accordance with ASTM F543 including insertion testing, insertion/removal torque, and static axial pullout
- Engineering analysis comparison of mechanical strength
- Pyrogenicity testing (LAL method), with results demonstrating bacterial endotoxins less than 20 EU/device in accordance with ANSI/AAMI ST72:2011/R2016

The results of these tests indicate that the Multi-Drive Interference Screw System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the Multi-Drive Interference Screw System is substantially equivalent to the identified predicate devices. The subject device has similar design, similar dimensions, and uses similar or identical materials. The subject device has the same indications for use and intended use, as well as similar technological characteristics (threaded screws in a range of diameters and lengths with a mating interface and central cannulation hole). The subject screw incorporates a multi-drive mating interface while the predicates utilize a single drive, and although this multi-drive offers additional options for insertion/removal, it utilizes the equivalent operating principle and function. These technological characteristics have undergone testing/analysis to ensure the subject device is equivalent to the predicates.

CONCLUSION

Based on the testing performed, including engineering analysis of mechanical strength, 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 Multi-Drive Interference Screw System are assessed to be substantially equivalent to the predicate devices.