March 25, 2026

Nvision Biomedical Technologies, Inc.
Marisa Zink
In-house Counsel
4590 Lockhill Selma Rd.
San Antonio, Texas 78249

Re: K260291
Trade/Device Name: Vortex5 Tailor's Bunion Correction 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: January 29, 2026
Received: January 29, 2026

Dear Marisa Zink:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

CHRISTOPHER FERREIRA -S

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.

510(k) Number *(if known)*
K260291

Device Name
Vortex5 Tailor's Bunion Correction System

Indications for Use *(Describe)*
The Vortex5 Tailor's Bunion Correction System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the toes (such as 5th metatarsal osteotomies for the correction of Tailor's Bunion). The system may be used in both adults and adolescent patients (13-21 years of age).

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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510(k) Summary

Prepared on: 2026-03-24

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Nvision Biomedical Technologies, Inc.
Applicant Address	4590 Lockhill Selma Road San Antonio TX 78249 United States
Applicant Contact Telephone	210-870-6261
Applicant Contact	Mrs. Marisa Zink
Applicant Contact Email	marisazink@nvisionbiomedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Vortex5 Tailor's Bunion Correction System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC (CLASS 2)

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202657	Javelin Tailor's Bunion Fixation System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The Vortex 5 Tailor's Bunion Correction System is a single-use bone Correction device intended to be permanently implanted. The system consists of an additively manufactured titanium alloy plate and machined screws that provide correction for 5th metatarsal osteotomies for the correction of Tailor's Bunion.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Vortex5 Tailor's Bunion Correction System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the toes (such as 5th metatarsal osteotomies for the correction of Tailor's Bunion). The system may be used in both adults and adolescent patients (13-21 years of age).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for the subject device and the predicate device are the same.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device has a similar design, similar dimensions, and uses similar or identical materials as the devices cleared in K202657, K182949, and K171558. The subject device also has the same intended use, as well as similar technological characteristics as these predicates. The Indications for Use are equivalent and any minor differences in wording choices are insignificant. These technological characteristics have undergone testing and engineering analysis to ensure the device is as safe and effective as the predicates. Further, the subject plates and screws incorporate equivalent features such as screw-receiving holes, tapered end, and locking screws. The

subject implant dimensions fall within the predicate ranges, including diameter, thickness, width, and length.

Based on the testing performed, including static and dynamic bending, static torsion, and engineering analysis 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 Vortex5 Tailor's Bunion Correction System are assessed to be substantially equivalent to the predicate devices.

Nvision believes that the Vortex5 Tailor's Bunion Correction System is substantially equivalent to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

No FDA performance standards have been established for The Vortex5 Tailor's Bunion Correction System. The device mechanical performance was tested in accordance with recognized consensus standards and current industry practice. Engineering analysis, static and dynamic bending, pullout and shear tests were completed for a substantial equivalence determination.

Engineering analysis demonstrates that the Vortex5 Tailor's Bunion Correction System does not create a worst-case relative to the predicate systems and thus confirms substantial equivalence with respect to mechanical performance.