April 1, 2026

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

Re: K253718
Trade/Device Name: enHAnce PEEK Bunion 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
Dated: March 10, 2026
Received: March 11, 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,

Thomas Mcnamara -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.

Submission Number *(if known)*

K253718

Device Name

enHAnce PEEK Bunion System

Indications for Use *(Describe)*

The enHAnce PEEK Bunion System is intended for fixation of osteotomies and corrective procedures of the hallux and associated disorders, such as hallux valgus.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K253718

510(k) Summary

Prepared on: 2026-03-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Nvision Biomedical Technologies, Inc.
Applicant Address	4590 Lockhill Selma Rd. San Antonio TX 78249 United States
Applicant Contact Telephone	2108706261
Applicant Contact	Mrs. Marisa Zink
Applicant Contact Email	marisazink@nvisionbiomed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	enHAnce PEEK Bunion 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

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211650	Radian MIS Bunion System	HRS
K192356	Novastep Airlock Osteosynthesis Implant System	HRS
K190658	CrossRoads MINIBunion System	HRS
K250646	Impact PEEK Union Nail	HTY
K241014	Biomet Kirschner Wires (K-Wires)	HTY

Device Description Summary

21 CFR 807.92(a)(4)

The enHAnce PEEK Bunion System is a single-use bone fixation device intended to be permanently implanted. The system consists of a plate and 3.0mm diameter pins that provide fixation for the first metatarsal in the correction of a bunion. The plate and pins are manufactured from HA Enhanced PEEK, are cannulated, and allow for intramedullary insertion and fixation at the proximal end. The plate has four pin-receiving holes with a stem portion. It is designed to allow for intramedullary insertion of the stem portion and fixation via the pins at the distal end. The three distal pins allow for medial insertion and the one proximal pin allows for metatarsal shaft fixation

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The enHAnce PEEK Bunion System is intended for fixation of osteotomies and corrective procedures of the hallux and associated disorders, such as hallux valgus.

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 enHAnce Bunion device has the equivalent intended use/indications for use and equivalent technological characteristics as the cleared predicates. The subject device has a similar design with bone plates that can equivalently accommodate use with integrated pins. The subject device is manufactured from HA enhanced PEEK and HA enhanced PEEK pins, which is equivalent to the devices cleared in K211650, K250646, and K192356. The K211650 and K192356 devices incorporate equivalent features such as an angled plate or plate and stem, screw or pin-receiving holes, and intramedullary fixation. The K250646 device incorporates equivalent features such as the HA enhanced PEEK material and the cylindrical stem for fixation. The subject implant dimensions fall within the predicate ranges, including thickness, width, and length.

Based on the testing performed, including static and dynamic bending, along with 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 enHAnce PEEK Bunion System are assessed to be substantially equivalent to the predicate devices.

Nvision believes that the enHAnce PEEK Bunion 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 enHAnce PEEK Bunion System. The device mechanical performance was tested in accordance with recognized consensus standards and current industry practice. ASTM F382-24 four-point static and fatigue bend testing was conducted against the predicates. Engineering analysis, static and dynamic bending, pushout and axial insertion tests were completed for a substantial equivalence determination.

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