September 18, 2026

Nvision Biomedical Technologies
Marisa Zink
In-House Counsel
12449 Silicon Dr.
San Antonio, Texas 78249

Re: K262098
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: June 22, 2026
Received: June 22, 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

For: 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262098

Please provide the device trade name(s).

EnHAnce PEEK Bunion System

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K262098

510(k) Summary

Prepared on: 2026-09-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Nvision Biomedical Technologies
Applicant Address	12449 Silicon Drive 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
K253718	enHAnce PEEK Bunion System	HRS
K241014	K-Wire	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 pins that provide fixation for the first metatarsal in the correction of a bunion. The plate and pins are both manufactured from HA Enhanced PEEK (ASTM F2026). Both the enHAnce PEEK Bunion Plate cleared in K253718 and the subject MIS PEEK Bunion Plate are designed to allow for intramedullary insertion of the stem portion. While the originally cleared plate has pin receiving holes, the subject device does not. The originally cleared plate and the subject MIS plate are both cannulated and provided in one size and configuration that can be used across all patient anatomy, including left and right feet.

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)

Nvision believes that the subject enHAnce MIS PEEK Bunion System is substantially equivalent to Nvision's own predicate device (K253718), and the fundamental scientific technology remains unchanged. The system modifications are not due to any complaint, nor are they based on a corrective fix to the device. Rather, the primary reason for these updates is to make the system more accessible for surgeons who are performing the procedure differently. The modification is:

1. Addition of MIS Bunion Implant: add a bunion implant configuration for minimally invasive bunion surgery to the already existing system consisting of a bunion implant not intended to be used for minimally invasive surgery in the previously cleared enHAnce PEEK Bunion System.

The enHAnce device is provided non-sterile in a sterilization case for subsequent steam sterilization at a healthcare facility prior to use (as cleared in K253718). Alternately, the enHAnce device can be terminally gamma-sterilized in a sealed sterile barrier package. The enHAnce devices may only undergo one method of sterilization and are not intended to be reprocessed.

Technological Comparison

21 CFR 807.92(a)(6)

The subject enHAnce implants maintain similar features as the previously cleared enHAnce device, including the same material of construction (PEEK HA), plate feature, stemmed portion of implant, etc. In addition, the MIS PEEK Bunion implant does not impose a new worst-case concerning size compared to the previously cleared implant, thus not affecting its mechanical strength or performance. Furthermore, the subject implant is used with some of the same instruments and new instruments very similar to the original enHAnce instruments. The changes in the instrumentation were made to accommodate the new MIS PEEK Bunion Implant, as it follows its own technique based on the surgeon's preference.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Engineering Analysis

Engineering analysis of the device characteristics demonstrated equivalence to the predicate devices with respect to mechanical performance. Key parameters for the worst-case subject enHAnce MIS PEEK Bunion, using the same criteria as the initial submission, were compared to those of the enHAnce PEEK Bunion to verify that the subject device system does not create a new global worst case and thus remained substantially equivalent to the predicates.

A Design Verification Summary is presented in Table 18.1. Verification results demonstrated that the performance characteristics of the worst-case subject enHAnce MIS PEEK Bunion are at least equivalent to those of the previously cited predicate. Both devices have equivalent dimensions and features, however variations in several parameters result in the predicates having reduced mechanical properties relative to the enHAnce PEEK Bunion System. Overall, the subject and predicate devices would have at least equivalent mechanical performance and would equivalently resist loads in vivo.

Furthermore, the subject and predicate devices are manufactured equivalently using conventional machining, cleaning, and surface treatments. They are also all equivalently sterilized, which does not raise questions of equivalence because the performance of Enhanced PEEK HA is not negatively impacted by steam sterilization or gamma radiation.

Conclusion: Engineering Analysis demonstrates that the subject enHAnce MIS PEEK Bunion does not create a new worst-case relative to the predicate systems and thus confirms substantial equivalence with respect to mechanical performance.