June 11, 2025

Nvision Biomedical Technologies
Erin Lansdale
Senior Project Engineer
4590 Lockhill Selma Rd
San Antonio, Texas 78249

Re: K250646
Trade/Device Name: Impact PEEK Union Nail System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: May 12, 2025
Received: May 12, 2025

Dear Erin Lansdale:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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, MS
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)*

K250646

Device Name

Impact PEEK Union Nail System

Indications for Use *(Describe)*

The Impact PEEK Union Nail System is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

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) Summary

DATE PREPARED
January 30, 2025

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: Erin Lansdale, Senior Project Engineer
Telephone: (210) 598-5657
Email: erinlansdale@nvisionbiomed.com

PROPRIETARY NAME OF SUBJECT DEVICE
Impact PEEK Union Nail System

COMMON NAME
PEEK, Pin, Fixation

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

PREMARKET REVIEW
OHT6/DHT6 - Division of Division of Restorative, Repair, and Trauma Devices
Orthopedic Panel

INDICATIONS FOR USE
The Impact PEEK Union Nail System is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

DEVICE DESCRIPTION
The Impact PEEK Union Nail System contains 3.0mm - 4.5mm diameter, 50mm long pins manufactured from HA Enhanced PEEK (ASTM F2026). The implants are designed with strategically placed ridges to improve initial stability and cannulated structure to simplify insertion over a k-wire. Additionally, it was designed to include tantalum pins to ensure optimal imaging visibility for device placement accuracy.

PREDICATE DEVICE IDENTIFICATION
The Impact PEEK Union Nail System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K133932	Inion FreedomPin	✓
K181180	OSSIO Pin Product Family	

SUMMARY OF NON-CLINICAL TESTING
No FDA performance standards have been established for the Impact PEEK Union Nail System. The following tests were performed to demonstrate substantial equivalence based on recognized consensus standards and current industry practice:

- Static and Dynamic Bending, Axial Pullout (ASTM F1264-16, ASTM F543-17)
- Shear Testing (ASTM D2344)

The results of these tests, as well as engineering analysis of device characteristics, indicate that the Impact PEEK Union Nail System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES
Nvision believes that the Impact PEEK Union Nail System is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design and similar dimensions as the devices cleared in K133932 and K181180 but differs because it is manufactured from HA Enhanced PEEK. 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.

CONCLUSION
Based on the testing performed, including bending, axial pullout, and shear testing, as well as engineering analysis of device characteristics, it can be concluded that the subject device The Impact PEEK Union Nail System 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 are assessed to be substantially equivalent to the predicate devices.