



November 18, 2025

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

Re: K253423

Trade/Device Name: ToeJack MIS 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: September 25, 2025
Received: September 25, 2025

Dear Marisa Zack:

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,

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

Submission Number (if known)

K253423

Device Name

ToeJack MIS Bunion System

Indications for Use (Describe)

The ToeJack MIS 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.

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510(k) Summary

Prepared on: 2025-11-17

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	(210) 870-6261
Applicant Contact	Mrs. Marisa Zink
Applicant Contact Email	marisazink@nvisionbiomed.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	ToeJack MIS Bunion System
Common Name	Plate, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
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
K181872	CrossRoads Extremity MIS Bunion System	HRS
K172178	Trilliant Surgical Minimally Invasive Bunion Plating System	HRS

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The ToeJack MIS Bunion System is a single-use bone fixation device intended to be permanently implanted. The system consists of a titanium alloy plate and locking 3.0mm diameter titanium screws that provide fixation for the first metatarsal in the correction of a bunion. Specifically, the plate has 4 screw-receiving holes. It is designed to allow for intramedullary insertion of the proximal shaft with 2 screw fixation and extramedullary medial insertion of the 2 distal screws. Further, the device is provided with a screw targeting insertion guide.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The ToeJack MIS 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 ToeJack 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 bone screws. The subject device is manufactured from titanium alloy and titanium alloy bone screws, which is equivalent to the devices cleared in K211650 and K181872. The K172178 device incorporates equivalent features such as an angled plate, screw-receiving holes, locking screws and intramedullary fixation. The subject implant dimensions fall within the predicate ranges, including thickness, width, and length. The differences in technology characteristics include the minor differences in plate geometry and location of the bone screws.

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 ToeJack MIS Bunion System are assessed to be substantially equivalent to the predicate devices.

Nvision believes that the ToeJack MIS 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 ToeJack MIS Bunion System. The device mechanical performance was tested in accordance with recognized consensus standards and current industry practice. Engineering analysis, ASTM F543 screw pullout and torsion testing, and static and dynamic four-point bend testing (similar to ASTM F382) to evaluate construct strength and stiffness was completed to demonstrate substantial equivalence for mechanical performance.

In conclusion, non-clinical testing and analysis demonstrates that the ToeJack MIS Bunion System does not create a worst-case relative to the predicate systems and thus confirms substantial equivalence.