



November 24, 2021

Nvision Biomedical Technologies, Inc
% Analaura Villarreal-Berain
Extremity Project Engineer
Nvision Biomedical Technologies
4590 Lockhill Selma
San Antonio, Texas 78249

Re: K211650

Trade/Device Name: The Radian 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: October 27, 2021
Received: October 28, 2021

Dear Analaura Villarreal-Berain:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,



Shumaya Ali -S

Shumaya Ali, M.P.H.

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

510(k) Number (if known)

K211650

Device Name

Radian MIS Bunion System

Indications for Use (Describe)

The Radian 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)

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510(k) Summary

DATE PREPARED

November 23, 2021

MANUFACTURER AND 510(k) OWNER

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PROPRIETARY NAME OF SUBJECT DEVICE

Radian MIS Bunion System

COMMON NAME

Bone Plate

DEVICE CLASSIFICATION

Single/multiple component metallic bone fixation appliances and accessories

(Classification Regulations: 21 CFR 888.3030, Product Codes: HRS, Class: II)

PREMARKET REVIEW

Orthopedic Device Panel

INDICATIONS FOR USE

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

DEVICE DESCRIPTION

The Radian MIS Bunion System is a single-use bone fixation device intended to be permanently implanted. The system consists of a titanium alloy plate and screws that provide fixation for the first metatarsal in the correction of a bunion. The plate has 4 screw-receiving holes. It is designed to allow for intramedullary insertion of the 2 proximal screws and medial insertion of the 2 distal screws. The plate is provided in 1 size and 1 configuration that can be used across all patient anatomy. The locking 3.0mm diameter titanium screws are designed in lengths of 14mm to 30mm in increments of 2mm. The system is provided non-sterile.

PREDICATE DEVICE IDENTIFICATION

The Radian MIS Bunion System is substantially equivalent to the following predicates:

<i>510(k) Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Predicate</i>
K212487	In2Bones USA CoLink Vallux Plating System	Primary
K172178	Trilliant Surgical LTD– Minimally Invasive Bunion Plating System	Additional
K181872	CrossRoads Extremity Systems, LLC – MIS Bunion System	Additional
K202657	Nvision Biomedical’s Javelin Tailor’s Bunion Fixation System	Reference

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Radian MIS Bunion System. The following testing was performed:

- Static and dynamic bending (per ASTM F382)
- Engineering analysis to evaluate screw mechanical strength

The results of these tests indicate that the Radian MIS Bunion System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the Radian MIS Bunion System is substantially equivalent to the predicate devices. The subject plates are similar to the predicates in that the geometry, thicknesses and lengths are similar, they are intended for use with ancillary screws, and they incorporate the similar number of ancillary screws. Furthermore, the ancillary screws are similar in size. The implants from the Radian MIS Bunion System are manufactured using Titanium and the instruments using medical grade Stainless Steel, identical to Javelin Tailor’s Bunion Fixation System (K202657).

CONCLUSION

Based on the testing performed, including static and dynamic bending, and engineering analysis, 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 Radian MIS Bunion System are assessed to be substantially equivalent to the predicate devices.