February 5, 2025

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

Re: K242896
Trade/Device Name: Caliber Intramedullary Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 7, 2025
Received: January 7, 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,

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

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)*

K242896

Device Name

Caliber Intramedullary Fixation System

Indications for Use *(Describe)*

The Caliber Intramedullary Fixation System is indicated to be used to repair an acute fracture, mal-union or non-union of the clavicle.

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.

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"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

February 5, 2025

MANUFACTURER AND 510(k) OWNER
Nvision Biomedical Technologies, INC
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San Antonio, TX 78249, USA
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Official Contact: Erin Lansdale
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PROPRIETARY NAME OF SUBJECT DEVICE
Caliber Intramedullary Fixation System

COMMON NAME
Smooth or threaded metallic bone fixation fastener

DEVICE CLASSIFICATION
Screw, fixation, bone
(Classification Regulations: 21 CFR 888.3040; Product Codes: HWC [primary], JDW; Class: II)

PREMARKET REVIEW
Office of Orthopedic Devices (OHT6); Restorative, Repair and Trauma Devices (DHT6C)

INDICATIONS FOR USE
The Caliber Intramedullary Fixation System is indicated to be used to repair an acute fracture, mal-union or non-union of the clavicle.

DEVICE DESCRIPTION
The Caliber Intramedullary Fixation System is an intramedullary bone fixation screw system used to repair an acute fracture, mal-union or non-union of the clavicle. The intramedullary implant consists of a cannulated screw with distal and proximal threads, a cross-screw receiving hole and a screw head. The diameter ranges from 4.5mm to 5.0mm in lengths from 50mm to 120mm. Additionally, the subject device is self-drilling and self-tapping and is made from Titanium Alloy.

PREDICATE DEVICE IDENTIFICATION

The Caliber Intramedullary Fixation System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K083144	Acumed Clavicle Screw System	✓
K182949	Healix Compression Screw System	
K103001	DePuy Orthopaedics, Inc, Rockwood Clavicle Pin	

SUMMARY OF NON-CLINICAL TESTING

The Guidance for Industry and Food and Drug Administration Staff - "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway" have been established for the Caliber Intramedullary Fixation System. The following tests were performed to demonstrate safety based on recognized consensus standards and current industry practice:

- Torsion, driving torque, and axial pullout (per ASTM F543)
- Static and dynamic bending (per ASTM F1264)

The results of these tests, as well as engineering analysis of device characteristics, indicate that Caliber Intramedullary Fixation System is equivalent to specified standards.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the Caliber Intramedullary Fixation System is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has a similar design, similar dimensions, and uses similar or identical materials as the devices cleared in K083144, K182949, and K103001. The subject device also has the same intended use, as well as similar technological characteristics (self-tapping threads, cannulation) 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 static bending, dynamic bending, torsion, driving torque, and axial pullout, as well as 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 Caliber Intramedullary Fixation System are assessed to be substantially equivalent to the predicate devices.