



April 2, 2025

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

Re: K250613

Trade/Device Name: SnapHammer Hammertoe Correction 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 13, 2025
Received: February 28, 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

Indications for Use

Submission Number (if known)

K250613

Device Name

SnapHammer Hammertoe Correction System

Indications for Use (Describe)

The SnapHammer Hammertoe Correction System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. Cannulated implants in the SnapHammer Hammertoe Correction System can be used with K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

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

DATE PREPARED

02/28/2025

MANUFACTURER AND 510(K) OWNER

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PROPRIETARY NAME OF SUBJECT DEVICE

SnapHammer Hammertoe Correction System

COMMON NAME

Screw, Fixation, Bone

DEVICE CLASSIFICATION

Smooth or Threaded Metallic Bone Fixation Fastener

(Classification Regulations: 21 CFR 888.3040, Product Codes: HWC, Class: II)

PREMARKET REVIEW

Orthopedic Device Panel

INDICATIONS FOR USE

The SnapHammer Hammertoe Correction System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. Cannulated implants in the SnapHammer Hammertoe Correction System can be used with K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

DEVICE DESCRIPTION

The SnapHammer Hammertoe Correction System is comprised of an additively manufactured titanium fixation device attached to a snap-off post. The snap-off post aids in a quick insertion and snaps off after implant has been threaded in. The implants are offered in Ø3.0mm and

Ø3.50mm diameters and in lengths ranging from 12mm to 15mm. The system includes drills, implant inserters, and sizers manufactured from medical grade stainless steel.

PREDICATE DEVICE IDENTIFICATION

The SnapHammer Hammertoe Correction System is substantially equivalent to the following predicates:

<i>510(k) Number</i>	<i>Predicate Device Name / Manufacturer</i>	<i>Primary Predicate</i>
K231453	Nvision Biomedical's SnapHammer Hammertoe Correction System	✓

Nvision Biomedical's Quantum (K210424) and Healix (K182949) are also cited in this submission as a reference predicate device.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the SnapHammer Hammertoe Correction System. The following was performed to demonstrate safety per methods of the previous submission:

- Engineering analysis comparing device characteristics including materials, intended use and processes (cleaning and sterilization methods)
- The steam sterilization process has been validated per ISO 17665-1 & 17665-2 to a sterility assurance level of 10^{-6}

The results of this comparison indicate that SnapHammer Hammertoe Correction System is substantially equivalent to the predicate devices.

EQUIVALENCE TO PREDICATE DEVICES

Nvision believes that the SnapHammer Hammertoe Correction System modification is substantially equivalent to the predicate devices. The subject implants maintain the same features as the previously cleared devices, but steam sterilization is being added as an alternative sterilization method, which is commonly used for medical devices such as the predicates. This modification does not change the intended use or performance of the device and does not raise additional questions of substantial equivalence. These technological characteristics have undergone a comparison of characteristics to ensure the device is as safe and effective as the predicates.

CONCLUSION

Based on the comparison 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 SnapHammer Hammertoe Correction System options are assessed to be substantially equivalent to the predicate devices.