October 17, 2025

SiNAPTIC Surgical
Brian Hockett
Vice President of Quality and Regulatory
1885 West 2100 South
Slat Lake City, Utah 84119

Re: K252254
Trade/Device Name: Osteotomy Wedge System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PLF
Dated: July 21, 2025
Received: July 21, 2025

Dear Brian Hockett:

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, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252254

Please provide the device trade name(s).

Osteotomy Wedge System

Please provide your Indications for Use below.

The SiNAPTIC Osteotomy Wedge System is intended to be used for internal bone fixation for fractures or osteotomies in the ankle and foot, such as:
1. Opening wedge osteotomies of the bones of the foot, including osteotomies for Hallux Valgus
2. Opening wedge of the medial cuneiform or Cotton osteotomies.
3. Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z-Osteotomy)
4. Metatarsal Cuneiform osteotomies
5. Nonunion of arthrodesis of the Midfoot including Metatarsal Cuneiform osteotomies (TMT or Lapidus)
6. Hindfoot osteotomies such as Ankle fusion and Subtalar fusion

The Osteotomy Wedge System MTP Wedges are intended to be used for internal fixation of metatarsal bones that have been surgically prepared (osteotomy) for correction of deformity.

The Osteotomy Wedge System is indicated for use with supplemental fixation.

The Osteotomy Wedge System is not indicated for use in the spine.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

SiNAPTIC SURGICAL

510(k) SUMMARY

Submitter Information

Submitter's Name:	SiNAPTIC Surgical, LLC
Address:	1885 West 2100 South Salt Lake City, UT 84119
Phone Number:	(855) 839-3500
Prepared By:	Brian Hockett
Contact Person:	Brian Hockett
Date Prepared:	7/17/2025

Device Information

Trade Name:	Osteotomy Wedge System
Common Name:	Bone Wedge
Classification:	Class II per 21 CFR 888.3030 Panel: Orthopedic, Product Code: PLF

Predicate Device Identification

510(k) Number	Device Name	Predicate
K243231	Nvision Biomedical's Trigon HA Stand-Alone Wedge Fixation System	Primary
K240461	AMES's Medical OsteoSinter Evans and Cotton Wedges	Additional
K201314	Restor3d Utility Wedge	Additional
K220513	CTL Medical Nitro Interbody Fusion Cage System Family	Reference

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The Osteotomy Wedge System is not indicated for use in the spine.

Device Description

The Osteotomy Wedge System devices are a sterile, single use Silicon Nitride (Si_3N_4) implants. The wedges are designed in a variety of shapes, each available in multiple footprints and thickness. The Osteotomy Wedge System is intended to be used for internal bone fixation for opening or lengthening osteotomies in the foot and ankle. The

wedges contain an insertion feature as well as a central, open area for packing graft material or insertion of supplemental fixation.

Summary of Non-Clinical Data

No FDA performance standards have been established for the Osteotomy Wedge System. The device was subjected to the following bench performance tests to support the assertation of substantial equivalence and evidence that no new safety or effectiveness concerns were raised:

- Static compressive strength
- Dynamic compressive strength
- Static compression shear strength
- Expulsion testing

The safety and effectiveness of the Osteotomy Wedge system is adequately supported by testing, substantial equivalence information, materials information and comparison of to the predicate device.

Summary of Equivalence to Predicate Devices

The Osteotomy Wedge system is substantially equivalent to the predicate devices. The subject implants have similar shapes, sizes and features as the previously cleared devices, including similar mechanism of fixation and principles of action. The devices also have the same indications for use. These technological characteristics have undergone a comparison of characteristics to ensure the device is as safe and effective as the predicates.

Conclusion

Although the Osteotomy Wedge System differs from the predicate in the device material, the devices have similar design / physical characteristics, intended use, and performance characteristics. The Osteotomy Wedge System does not raise different questions of safety or effectiveness. The Osteotomy Wedge System is substantially equivalent to the predicate device.