August 27, 2025

Astra OrthoMed, Inc.
℅ Justin Gracyalny
Regulatory Affairs Program Manager
Secure BioMed Evaluations
7828 Hickory Flat Hwy
Woodstock, Georgia 30188

Re: K251382
Trade/Device Name: Phoenix Sinus Tarsi Stent System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 28, 2025
Received: July 28, 2025

Dear Justin Gracyalny:

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251382

Please provide the device trade name(s).

Phoenix Sinus Tarsi Stent System

Please provide your Indications for Use below.

Phoenix Sinus Tarsi Stent is an implant stabilization device used in the treatment of talotarsal joint instability in adult and pediatric patients four years of age and older. The stent is designed to stabilize the talus to prevent excessive anterior, and/or medial, and/or plantarflexion of the talus, while allowing normal talotarsal joint motion.

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)

K251382
510(k) SUMMARY:
Phoenix Sinus Tarsi Stent System

Date Prepared	August 21, 2025
Sponsor	Astra OrthoMed 330 Franklin Road Suite 135A-213 Brentwood, TN 37027 586-604-9462
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	Phoenix Sinus Tarsi Stent System
Common Name	Sinus Tarsi Implant
Code –Classification	HWC - Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Primary Predicate	K142534 GraMedica LLC. HyProCure II
Reference Device	K042030 GraMedica LLC. HyProCure Subtalar Implant System K111834 Trilliant Surgical LTD Disco Subtalar Implant
Device Description	The Phoenix Sinus Tarsi Stent is a non-pyrogenic type IIB extra-osseous talotarsal stabilization (EOTTS) device used in the treatment of talotarsal joint instability per Graham Et al. EOTTS classification system. The stent system consists of an implant designed to be inserted into the sinus tarsi and has corresponding instrumentation to facilitate the insertion. All stents are manufactured from Ti-6Al-4V ELI per ASTM F136 and have 5 sizes with varying diameter.
Indications for Use Statement	Phoenix Sinus Tarsi Stent is an implant stabilization device used in the treatment of talotarsal joint instability. The stent is designed to stabilize the talus to prevent excessive anterior, and/or medial, and/or plantarflexion of the talus, while allowing normal talotarsal joint motion.

Comparison of Technological Characteristics

The Phoenix Sinus Tarsi Stent System is substantially equivalent to the legally marketed predicate devices in terms of intended use, design, materials of construction, mechanical safety and performance. The subject device indications for use include minor differences for clarification. Any differences in terminology do not create a change in the device and are simply clarification of terminology as compared to predicate device.

There are no significant technological differences between the subject and predicate device. The subject device uses the same material as the predicate and reference devices, offers sizes within the ranges offered by the predicate and reference devices, and all devices are manufactured using subtractive techniques. Any minor geometric differences are supported by performance testing.

Non-Clinical Performance Testing Summary

Performance testing for Phoenix Sinus Tarsi Stent System include:

- Screw Pullout Testing per ASTM F543
- Cantilever Bending Testing per ASTM 2193
- Endotoxin Testing per AAMI ST72 and USP <85>
- Sterilization Testing per ISO 11137-1, ISO 11137-2
- Cytotoxicity Testing per ISO 10993-5
- Biocompatibility Risk Assessment
- Packaging Shelf-Life Performance Testing per ISO 11607-1, ASTM F88/F88M, ASTM F2096, ASTM F1886/1886M

All testing showed the subject device performed as intended. All testing met applicable predetermined acceptance criteria. All testing supports the subject device is substantially equivalent to the predicate device.

Conclusions

Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.