December 2, 2024

Vilex, LLC
Chris Weaber
Consultant
111 Moffitt St.
McMinnville, Tennessee 37110

Re: K240475
Trade/Device Name: Hintermann Series H2 Total Ankle System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: October 18, 2024
Received: October 21, 2024

Dear Chris Weaber:

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,

Lixin Liu -S

Lixin Liu, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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.

510(k) Number *(if known)*
K240475

Device Name
Hintermann Series H2 Total Ankle System

Indications for Use *(Describe)*
The Hintermann Series H2 Total Ankle (Hintermann Series H2) system is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, replacing flexion and extension movement in the ankle joint, and allowing for movement at the replaced joint.

The Hintermann Series H2 is indicated as a total ankle replacement in primary or revision surgery of ankle joints damaged by:

- Systemic arthritis of the ankle (e.g., rheumatoid arthritis, hemochromatosis)
- Primary arthritis (e.g., degenerative disease)
- Secondary arthritis (e.g., post-traumatic, avascular necrosis, provided enough of the talus is preserved to support the implant)

The Hintermann Series H2 is also indicated for patients with a failed previous ankle surgery and revision surgeries following failed total ankle replacement or non-union/mal-union of the ankle arthrodesis, provided sufficient bone stock is present.

Note: In the United States, this device is intended for cemented use only.

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.

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510(k) Summary

Manufacturer: Vilex, LLC
111 Moffitt Street
McMinnville, TN 37110
Phone: 800-521-5002

Contact: Jessica Johnson
Manager, Quality & Sustaining Engineering

Primary Correspondent: Chris Weaber
Consultant

Date Prepared: November 27, 2024

Device Trade Name: Hintermann Series H2 Total Ankle System

Device Common Name: Tibial Component, Tibial Polyethylene Inlay, Talar Component

Classification: 21 CFR 888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis

Class II

Product Code: HSN

Device Description:
The Hintermann Series H2 Total Ankle System is a total ankle prosthesis designed to replace the ankle joint. The Hintermann Series H2 Total Ankle System includes the following implantable components.

- H2 Tibial Component
- H2 Tibial Polyethylene (PE) Inlay
- Hintermann Series Talar Component

The tibial and talar components are coated with plasma spray titanium on the cement contacting surfaces. These components are used together to address the indications as outlined.

Indications for Use:
The Hintermann Series H2 Total Ankle (Hintermann Series H2) System is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, replacing flexion and extension movement in the ankle joint, and allowing for movement at the replaced joint.
The Hintermann Series H2 is indicated as a total ankle replacement in primary or revision surgery of ankle joints damaged by:

- Systemic arthritis of the ankle (e.g., rheumatoid arthritis, hemochromatosis)

- Primary arthritis (e.g., degenerative disease)
- Secondary arthritis (e.g., post-traumatic, avascular necrosis, provided enough of the talus is preserved to support the implant)

The Hintermann Series H2 is also indicated for patients with a failed previous ankle surgery and revision surgeries following failed total ankle replacement or non-union/mal-union of the ankle arthrodesis, provided sufficient bone stock is present. Note: In the United States, this device is intended for cemented use only.

Predicate Devices:
The modified Hintermann Series H2 Total Ankle System is substantially equivalent to the primary predicate Hintermann Seiries H2 Total Ankle System (K171004) with respect to design, function and indications for use.

Comparison of Technological Characteristics:
The Hintermann Series H2 Total Ankle System's intended use, indications for use, and overall system design is identical between the subject and predicate device. Minor design changes were implemented on the tibial component, the material of the PE inlay was changed to Vitamin E blended UHMWPE, and additional smaller sizes for the tibial component, PE inlay and Talar component were added to the system. These changes do not raise different questions of safety and effectiveness and substantial equivalence is demonstrated through the engineering analysis and testing described below.

Discussion of Non-Clinical Testing/Performance Data:
The following testing and engineering analysis were provided in support of the substantial equivalence determination:

Mechanical Testing

- Range of Motion (per ASTM F2665-09)
- Locking Mechanism Testing (per ASTM F1814)
- Constraint Testing (ASTM F1223-20)
- Tibial Fatigue (per ASTM F1800-19e1)
- Contact Area/Contact Stress (per ASTM F2665-21)
- Wear (per ISO 22622-19)
- Implant Construct Fatigue (custom test)

Engineering Analysis

- Tibial Bone Fixation

Additionally, the following tests were performed on the subject Hintermann H2 Series Total Ankle System:

- Material Characterization for Vit E UHMWPE per FDA Guidance.
- MRI Safety Testing per ASTM F2052-21, ASTM F2213-17, ASTM F2119-13(17), ASTM F2182-19e2

Biocompatibility analyses was also performed to demonstrate the substantial equivalence of the subject device to the predicate, and the Hintermann Series H2 Total Ankle System is also in compliance with LAL testing requirements for orthopedic implant

Conclusion:
The information provided above supports that the Hintermann Series H2 Total Ankle System is as safe and effective as the predicate device. Although minor differences in design exist between the subject and predicate devices, the testing conducted supports that these differences do not raise any different questions of safety and effectiveness. Therefore, it is concluded that the Hintermann Series H2 Total Ankle System is substantially equivalent to the predicate device.