July 17, 2023

Vilex, LLC
Brock Johnson
President, Vilex, LLC
111 Moffitt Street
McMinnville, Tennessee 37110

Re: K230462
Trade/Device Name: OPTIX H2 Patient Specific Instrument System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSN, OYK
Dated: April 19, 2023
Received: April 21, 2023

Dear Brock Johnson:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230462

Device Name
OPTIX H2 Patient Specific Instrument System

Indications for Use *(Describe)*
The OPTIX H2 Patient Specific Instrument System is intended to be used as patient specific surgical planning and instrumentation to assist in the positioning of total ankle replacement components intraoperatively, and in guiding bone cutting. The OPTIX H2 Patient Specific Instrument is intended for use with Vilex's Hintermann Series H2 Total Ankle System and its cleared indications for use. The OPTIX H2 Patient Specific Instrument System is indicated for single use only and is generated from CT imaging data.

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

Device Trade Name	OPTIX H2 Patient Specific Instrument System
Date	02/17/2023
Sponsor	Vilex, LLC 111 Moffitt Street McMinnville, TN 37110
Contact Person	Brock Johnson President (801)916-4157 brock.johnson@vilex.com
Device Common Name	OPTIX H2 PSI System
Device Classification	Class II
Classification Name	Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulation	21 CFR 888.3110
Device Regulation Panel	Orthopedic
Device Product Code	HSN, OYK
Predicate Device	Hintermann Series H2 Total Ankle System, K171004

Purpose:
The purpose of this Traditional 510(k) submission is to gain clearance for the OPTIX H2 Patient Specific Instrument System.

Device Description:
OPTIX H2 Patient Specific Instrument System is patient-specific guides created to fit the contours of the patient's distal tibial and proximal talar anatomy. The guides and models are designed and manufactured from patient imaging data (CT) and are made from biocompatible nylon. The surgical guides in combination with Hintermann reusable instruments, facilitate the positioning of the Hintermann Series H2 Total Ankle implants. Vilex's OPTIX H2 PSI System produces a variety of patient specific outputs including surgical guides, anatomic models, and case reports.

Indications for Use:
The OPTIX H2 Patient Specific Instrument System is intended to be used as patient specific surgical planning and instrumentation to assist in the positioning of total ankle replacement components intraoperatively, and in guiding bone cutting. The OPTIX H2 Patient Specific Instrument System is intended for use with Vilex's Hintermann Series H2 Total Ankle System and its cleared indications for use. The OPTIX H2 Patient Specific Instrument System is indicated for single use only and is generated from CT imaging data.

Technological Characteristics:
The OPTIX H2 Patient Specific Instrument System is indicated for use in conjunction with the Hintermann Series H2 Total Ankle System. The OPTIX H2 Patient Specific Instrument System

is intended to aid with the bone preparation of the H2 System. After bone preparation, the Hintermann H2 Total Ankle System surgical technique is followed for implantation of the Hintermann H2 implants. Therefore, the technological characteristics of the devices implanted with the OPTIX H2 PSI System and the predicate are identical.

The OPTIX H2 PSI System is comprised of single use instruments composed of DuraForm ProX PA® (SLS) and stainless steel. The predicate device uses reusable stainless-steel and polymer instrumentation. The proper biocompatibility endpoints of ISO 10993-1 have been evaluated for DuraForm ProX PA® and have shown no questions with respect to safety. Both the OPTIX H2 PSI System and the predicate device instrumentation are steam sterilized by the end user prior to use.

The OPTIX H2 PSI System is comprised of patient specific instruments generated from CT imaging. The predicate device uses instrumentation that is not patient specific. The OPTIX H2 PSI System allows the surgeon to create an operating plan before the surgery to visualize how the final implants and instruments will interface with patient anatomy. The OPTIX H2 PSI System also provides patient specific bone models to allow the surgeon to confirm the correct placement of the PSI Cut Guides. The preoperative plan and bone models facilitate the preparation of the bone for the Hintermann H2 Total Ankle Implants. The design of the patient specific guides, models, and pre-operative plan is software-assisted. The predicate device does not contain a preoperative plan, bone models, or software-assisted design.

The technological differences between the OPTIX H2 PSI System and the predicate device allow the OPTIX H2 PSI System to facilitate the implantation of the predicate device. These technological differences are considered minor and raise no questions of safety or effectiveness.

Assessment of performance data:
Validation testing was performed for the OPTIX H2 PSI System in comparison with the Hintermann H2 System. The objective of this testing was to demonstrate that the OPTIX H2 PSI System allows for an equivalent implantation of the Hintermann Series H2 Total Ankle System implants as compared to the Hintermann instrumentation. To accomplish this objective, Hintermann H2 Total Ankle surgical procedures were performed head-to-head using the OPTIX H2 PSI System and the Hintermann H2 Total Ankle System instrumentation.

An analysis of the surgical procedures performed during the validation lab showed that the OPTIX H2 PSI System does provide an equivalent implantation of the Hintermann Series H2 Total Ankle implants as compared to the Hintermann Series H2 instrumentation. In addition, the OPTIX H2 PSI System is shown to satisfy the clinically justified acceptance criteria of the Hintermann Series H2 Total Ankle System. Therefore, it is concluded that the subject device is substantially equivalent to the predicate device with respect to its mechanical performance.

Debris generation testing was performed for the OPTIX H2 PSI guides in a benchtop setting. The results were compared against a legally marketed device composed of a similar patient-specific

instrumentation system. The debris generated by the OPTIX H2 PSI System was found to be acceptable compared to the legally marketed device.

Conclusion:
Based upon the similarities of the OPTIX H2 Patient Specific Instrument System and the predicate device, the OPTIX H2 Patient Specific Instrument System is substantially equivalent to the predicate device. The similarities in technological characteristics and performance data demonstrate substantial equivalence.