December 20, 2023

Enhatch, Inc.
Monica Williams
QA/RA Manager
226 Boulevard
Hasbrouck Heights, New Jersey 07604

Re: K230850
Trade/Device Name: United Orthopedic Knee Patient Specific Instrumentation
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: OOG, PBF, LLZ
Dated: March 24, 2023
Received: March 28, 2023

Dear Monica Williams:

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.

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, 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)*
K230850

Device Name
United Orthopedic Knee Patient Specific Instrumentation

Indications for Use *(Describe)*
The United Orthopedic Knee Patient Specific Instrumentation is indicated as an orthopedic instrument system to assist in the positioning of compatible total knee arthroplasty systems. It is comprised of surgical planning software (Intelligent Surgery Knee CT Segmentation Engine/Knee X-ray Segmentation Engine, and Implant Recognition Engine) intended to preoperatively plan the surgical placement of the United Orthopedics Knee implants on the basis of provided patient radiological images and 3D reconstructions of bones with identifiable anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. The United Orthopedic Knee Patient Specific Instrumentation is indicated for patients without severe bone deformities, such as a HKA greater than 15° or deformities due to prior fracture of the distal femur or proximal tibia.

The instruments are intended for use with the U2 Total Knee System when the clinical evaluation complies with its evaluation complies with its cleared indications for use. The instruments are intended for single 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.

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510(k) Summary

1. INTRODUCTION

This document contains the 510(k) summary for the **United Orthopedic Knee Patient Specific Instrumentation**. The content of this summary is based on the requirements of 21 CFR 807.92.

2. SUBMITTER

Name:	Enhatch, Inc.
Address:	226 Boulevard Hasbrouck Heights, NJ 07604 Phone: (201) 771-2034
Official Correspondent:	Monica Williams QA/RA Manager
Date Prepared:	November 20, 2023

3. DEVICE

Trade Name:	United Orthopedic Knee Patient Specific Instrumentation
Regulation Number:	21 CFR 888.3560
Regulation Name:	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class:	Class II
Product Code:	OOG, PBF, LLZ

4. PREDICATE DEVICES

Primary predicate device:

- X-PSI Knee System, Orthosoft (K171269)

Secondary predicate devices:

- VSP Orthopedics System, 3D Systems (K211244)
- United Orthopedic Corporation U2 Total Knee System (K051640)

5. DESCRIPTION OF THE DEVICE

The ***United Orthopedic Knee Patient Specific Instrumentation*** is comprised of: *United Orthopedics (UO) surgical guides* (hardware), *anatomical models* (physical replica), *Intelligent Surgery Knee CT Segmentation Engine / Intelligent Surgery Knee X-ray Segmentation Engine* (software), and *Intelligent Surgery Knee Implant Recognition Engine* (software). Enhatch is responsible for design and development of all three components of the system.

The subject device is intended to facilitate the implantation of the U2 Knee protheses under the U2 Knee System developed and distributed by United Orthopedics Corporation: U2 Total Knee System.

[THE SOFTWARE]

The *Intelligent Surgery Knee Segmentation Engine* consists of two imaging modalities, CT (*Knee CT Segmentation*) and X-ray (*Knee X-ray Segmentation*). The *Intelligent Surgery Knee CT Segmentation Engine* and *X-ray Segmentation Engine* are web applications that use deep learning algorithms to detect and extract region of interest (ROI) information (femur and tibia) from medical imaging data (DICOM). The segmentation engines generate 3D models which can be used for treatment planning of Total Knee Arthroplasty (TKA), design of surgical guides, or generation of 3D printed anatomical models.

The *Intelligent Surgery Knee Implant Recognition Engine* is a web application that uses an optimization algorithm as a treatment planning tool for total knee arthroplasty. It assists in selecting implant size and position, from a range of implants of a total knee implant system, using a range of run parameters based upon the TKA surgical technique of that system. The software identifies anatomical landmarks of the patient's bony anatomy and articular surface topographies to reference the position and alignment of the femoral and tibial implant components. This positioning and alignment in turn allows for design of surgical guides and of the ***United Orthopedic Knee Patient Specific Instrumentation***.

Note, these algorithms are static and non-adaptive; they do not alter their behavior over time based on user input.

[THE HARDWARE]

The *UO surgical guides* and *anatomical models* are patient-specific instruments designed to facilitate the implantation of the United Orthopedics Knee protheses. The *UO surgical guides* are designed based on preoperative plan generated by the software Intelligent Surgery Knee Implant Recognition Engine.

6. INDICATIONS FOR USE

The ***United Orthopedic Knee Patient Specific Instrumentation*** is indicated as an orthopedic instrument system to assist in the positioning of compatible total knee arthroplasty systems. It is comprised of surgical planning software (Intelligent Surgery Knee CT Segmentation Engine/Knee X-ray Segmentation Engine, and Implant Recognition Engine) intended to preoperatively plan the surgical placement of the United Orthopedics Knee implants on the basis of provided patient radiological images and 3D reconstructions of bones with identifiable anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. The United Orthopedic Knee Patient Specific Instrumentation is indicated for patients without severe bone deformities, such as a HKA greater than 15° or deformities due to prior fracture of the distal femur or proximal tibia. The instruments are intended for use with the U2 Total Knee System when the clinical evaluation complies with its cleared indications for use. The instruments are intended for single use only.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technical features of ***United Orthopedic Knee Patient Specific Instrumentation*** are substantially equivalent to the primary predicate, Orthosoft X-PSI Knee System (K171269), and secondary predicate devices, 3D Systems VSP Orthopedics System (K211244) and United Orthopedic Corporation U2 Total Knee System (K051640).

The subject device has similar indications for use as compared to the predicates. At a high level, the subject and predicate devices are based on the following same technological elements:

- Includes software as a medical device component
- Image transfer and manipulation via software to be used for 3D printing of anatomical models and guides for surgical planning
- Visualization of radiological images (CT and X-ray), image segmentation, and 3D reconstruction of bones
- Display and measurement evaluations of anatomical landmarks that must be viewed, accepted, or rejected by a clinician
- For use by prespecified clinical users

The following technological differences exists between the subject and predicate devices:

- Internal facing versus external user interface, ***United Orthopedic Knee Patient Specific Instrumentation*** software follows a SaaS preoperative planning workflow where Enhatch technicians interface directly with the software and provide end user outputs
- Segmentation edge detection versus manual outlining of patient contours, ***United Orthopedic Knee Patient Specific Instrumentation*** has the ability to semi-automatically identify bony contours for the alignment of the final algorithmic model using deep learning algorithms whereas predicate device
- Implant sizing / placement with an optimization algorithm versus manual user controls, ***United Orthopedic Knee Patient Specific Instrumentation*** does not allow end user to perform measurements in software but uses an optimization algorithm to find the approximate location of implant size / position approved by surgeon via a preoperative plan

The following table provides details of the ***United Orthopedic Knee Patient Specific Instrumentation*** as compared to the primary and secondary predicates.

Table – Comparison Summary

Technological Characteristics	**Subject Device: United Orthopedic Knee Patient Specific Instrumentation**	**Primary Predicate: Orthosoft X-PSI Knee System (K171269)**	**Predicate Device: 3D Systems VSP Orthopedics System (K211244)**	**Predicate Device: United Orthopedic Corporation U2 Total Knee System (K051640)**	**Comparison**
Indications for Use (IFU)	The ***United Orthopedic Knee Patient Specific Instrumentation*** is indicated as an orthopedic instrument system to assist in the positioning of compatible total knee arthroplasty systems. It is comprised of surgical planning software (Intelligent Surgery Knee CT Segmentation Engine/Knee X-ray Segmentation Engine, and Implant Recognition Engine) intended to preoperatively plan the surgical placement of	The X-PSI Knee System is indicated as an orthopedic instrument system to assist in the positioning of knee replacement components. It involves surgical planning software used pre-operatively to plan the surgical placement of the components on the basis of provided patient radiological images and 3-D reconstructed bones with identifiable placement anatomical landmarks, and surgical instrument	The VSP® Orthopedics System is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies for adult patients in the distal femur, tibia, and non-sacrum pelvis.	This device is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when	Substantially Equivalent All fundamental aspects of the indications for use are the same (e.g. visualization of radiological images, 3D reconstruction of bones and includes tools to improve visualization, positioning of knee replacement components, use of clinical judgement, use with fixed bearing knee replacement systems)

	the United Orthopedics Knee implants on the basis of provided patient radiological images and 3D reconstructions of bones with identifiable anatomical landmarks, and surgical instrument components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. The United Orthopedic Knee Patient Specific Instrumentation is indicated for patients without severe bone deformities, such as a HKA greater than 15° or deformities due to prior fracture of the distal femur or proximal tibia. The instruments are intended for use with the U2 Total Knee System when the clinical evaluation complies with its cleared indications for use. The instruments are intended for single use only.	components that include patient specific or customized guides fabricated on the basis of the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. The X-PSI Knee system is indicated for patients without severe bone deformities, such as a HKA greater than 15° or deformities due to prior fracture of the distal femur or proximal tibia. The X-PSI Knee System is to be used with the following fixed bearing knee replacement systems in accordance with their indications and contraindications: NexGen® CR, NexGen CR-Flex, NexGen CR-Flex Gender, NexGen LPS, NexGen LPS-Flex, NexGen LPS-Flex Gender, Persona® CR, Persona PS, Vanguard® CR and Vanguard PS. The patient specific guide components are intended for single-use only.		there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device system is designed for cemented use only.	
Device Class	Class II				Same
Device Code	OOG, PBF, LLZ	OOG, JWH, MBH,	PBF	JWH	Substantially

		LLZ			Equivalent
Patient Population	Adult patients	Patients without severe bone deformities	Adult patients	Skeletally mature patients	Substantially Equivalent
End User	Prespecified clinical users (orthopedic surgeons)				Equivalent
Image Modality	CT, X-ray	X-ray	CT	N/A	Substantially Equivalent
Software Processing	Image segmentation, implant predictability, dimensioning of digital representations of models, generation of PSI	Image segmentation, implant predictability, dimensioning of digital representations of models, generation of PSI	Image segmentation, dimensioning of digital representations of models, generation of PSI	N/A	Substantially Equivalent Software processing functionality is consistent
Preoperative Planning	Provides tool to improve visualization, generate 3D models and perform model measurements to choose, size, and position the implant	Provides tool to improve visualization, generate 3D models and perform model measurements to choose, size, and position the implant	Provides tool to improve visualization, generate 3D models	N/A	Substantially Equivalent Subject device tools for preoperative planning are consistent
Output	Patient specific anatomical models and guides (physical outputs); and patient specific surgical plans and digital files (digital outputs)	Patient specific anatomical models and guides (physical outputs); and patient specific surgical plans and digital files (digital outputs)	Patient specific anatomical models, templates, and guides (physical outputs); and patient specific surgical plans and digital files (digital or documentation outputs)	N/A	Substantially Equivalent Device outputs are consistent

8. SUMMARY OF PERFORMANCE TESTING

Safety and performance of ***United Orthopedic Knee Patient Specific Instrumentation*** has been evaluated and verified in accordance with software specifications and applicable performance standards through Software Development and Verification & Validation Procedures (ISO 14971, IEC 62304:2006 & A1:2016), User Requirements, and Federal Regulations and Guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "FDA Guidance on Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." The software contained in this device is considered to be of "moderate level of concern," since a failure or latent design flaw could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

United Orthopedic Knee Patient Specific Instrumentation has been evaluated through the following non-clinical testing:

- Segmentation System Testing
    - This testing was performed to verify and validate the accuracy of the software generated segmentation masks for CT and X-ray based DICOM data. The device passed the acceptance criteria and demonstrated satisfactory performance per the intended use.

- Model Verification Testing
    - This testing was performed to verify and validate the accuracy of the software generated 3-dimensional models from CT and X-ray based DICOM data. The device passed the acceptance criteria and demonstrated satisfactory performance per the intended use.

- Software System Testing
    - This testing was performed to verify and validate the accuracy of landmark detection, system usage and accuracy. All specimens were within the bounds of the acceptance criteria. The resulting output measurements from the system were within the bounds of the input parameters (input values produced expected output values). The device passed the acceptance criteria and demonstrated satisfactory performance per the intended use.

- Guide Wear Testing
    - This testing was performed to verify and validate the amount of wear debris generated from use of the surgical guides. The device passed the acceptance criteria of average weight loss and demonstrated satisfactory performance per the intended use.

- System Verification and Validation Test
    - This testing was performed to verify and validate the amount overall system performance in terms of system usage, and accuracy. Full use simulations tests using cadaver specimens were performed by multiple surgeons to verify and validate the overall system performance. The results demonstrated satisfactory performance per the intended use as in the predicate

In conclusion, ***United Orthopedic Knee Patient Specific Instrumentation*** performance testing has demonstrated the subject device's safety and effectiveness and meets its intended use statement.

CONCLUSION

The result of the comparison of the intended use/indications and technological characteristics of ***United Orthopedic Knee Patient Specific Instrumentation*** as compared to the primary predicate and secondary predicates demonstrate that ***United Orthopedic Knee Patient Specific Instrumentation*** is substantially equivalent to the chosen predicate devices. Additionally, the results of testing demonstrate that ***United Orthopedic Knee Patient Specific Instrumentation*** is as safe and effective as the predicate device and does not raise different questions relating to safety and/or effectiveness.