June 27, 2024

Unik Orthopedics, Inc.
Charlie Chi
Founder & CTO
701 Fortune Drive, Unit E
San Jose, California 95131

Re: K240327
Trade/Device Name: UNIKO PointCloud™ Knee Instruments
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Codes: JWH, OOG, MBH
Dated: April 5, 2024
Received: April 8, 2024

Dear Charlie Chi:

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2024.06.27 12:06:43 -04'00'

For: 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)*
K240327

Device Name
UNIKO PointCloud™ Knee Instruments

Indications for Use *(Describe)*
The UNIKO PointCloud™ Knee Instruments are intended to be used as a surgical instrument to assist in the positioning of Total Knee Replacement components intraoperatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient MRI scans.

The UNIKO PointCloud™ Knee Instruments are compatible with the femoral and tibial components of the DJO Surgical EMPWR 3D Knee System and the Maxx Orthopedics Freedom Total Knee System. The Indications for Use of the DJO Surgical EMPWR 3D Knee System and the Maxx Orthopedics Freedom Total Knee System remain the same as those cleared in the manufacturer's clearances for the implant system.

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Information:

Owner Name:	Unik Orthopedics, Inc.
Address:	1701 Fortune Drive, Unit E San Jose, CA 95131
Phone:	(408) 883-5842
Contact Person:	Charlie Chi, Ph.D.
Phone:	(408) 887-5842
Date Prepared:	21 June 2024

Device Information:

Classification:	Class II
Trade Name:	UNIKO PointCloud™ Knee Instruments
Common name:	Cutting Guide
Classification name:	Knee joint patellofemorotibial polymer/metal/ polymer semi-constrained cemented prosthesis Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulation number:	21 CFR 888.3560 and 21 CFR 888.3565
Classification Code:	JWH, OOG, MBH

Predicate Device:
The subject of this submission, the UNIKO PointCloud™ Knee Instruments, is substantially equivalent to the Primary Predicate, Stryker ShapeMatch Cutting Guides cleared by FDA through 510(k) K122053, and the Secondary Predicate, UNIKO PointCloud™ Knee Instruments which were cleared by FDA through 510(k) K193312. The subject device has the same intended use, indications for use, design, material, operational principles, and performance as the secondary predicate device, UNIKO PointCloud™ Knee Instruments. Additionally, the subject device has substantially equivalent intended use, indications for use, design, materials, and operational principles to the Primary Predicate, Stryker ShapeMatch Cutting Guides.

Device Description:
The purpose of this submission is to add an additional cleared knee implant system to the previously cleared UNIKO PointCloud™ Knee Instruments cleared through 510(k) K193312. The predicate device was cleared for compatibility with the DJO Surgical EMPWR 3D Knee System and this submission provides for additional compatibility with the Maxx Orthopedics Freedom Total Knee System

The UNIKO PointCloud™ Knee Instruments use the TKA surgical plan that is output from the Vault® System Surgical Planning Software which was previously cleared by FDA through K124051. The surgeon plans a primary total knee replacement surgery using the Vault System and the output data file from the individualized surgical plan is utilized by the UNIKO PointCloud™ Knee Instruments to create the necessary files for the production of patient specific cutting guides for the initial cuts to the distal femur and proximal tibia.

The UNIKO PointCloud™ Knee Instruments are patient specific cutting guides which are machined from polyoxymethylene material by the by means of customized off-the-shelf software. These guides (also called jigs) aid the surgeon in making the initial distal femoral and the initial proximal tibial bone cuts along with establishing the references for femoral orientations used during total knee arthroplasty surgery. The surgeon then continues the surgical procedure with the conventional knee instrumentation provided by the implant manufacturer for the implant and size specific cuts required for implantation of the femoral and tibial total knee implants.

The UNIKO PointCloud™ Knee Instruments are patient specific and are intended as single use instruments compatible with the TKA femoral and tibial components of the DJO Surgical EMPWR 3D Knee System and the Maxx Orthopedics Freedom Total Knee System. The Indications for Use of the DJO Surgical EMPWR 3D Knee System and the Maxx Orthopedics Freedom Total Knee System remain the same as those cleared in the manufacturer's clearance for those implant systems.

Intended Use / Indication for Use:
The UNIKO PointCloud™ Knee Instruments are intended to be used as a surgical instrument to assist in the positioning of Total Knee Replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient MRI scans.

The UNIKO PointCloud™ Knee Instruments are compatible with the femoral and tibial components of the DJO Surgical EMPWR 3D Knee System and the Maxx Orthopedics Freedom Total Knee System. The Indications for Use of the DJO Surgical EMPWR 3D Knee System and the Maxx Orthopedics Freedom Total Knee System remain the same as those cleared in the manufacturer's clearances for the implant system.

Substantial Equivalence:
Like the Primary Predicate, Stryker ShapeMatch Cutting Guides, and the Secondary Predicate, UNIKO PointCloud™ Knee Instruments, the subject UNIKO PointCloud™ Knee Instruments are intended to be used as a Knee Arthroplasty Implantation System. That is, a device accessory or set of device accessories that aids the surgeon in performing the implantation of the knee implant. Also, like both predicate devices, the UNIKO PointCloud™ Knee Instruments is indicated for use with femoral and tibial components of compatible FDA cleared total knee implant systems. See the table below for the specific implant systems for each of the predicate devices.

Technological Characteristics/Performance Data:
Substantial equivalence in materials and technological characteristics of the UNIKO PointCloud™ Knee Instruments and the predicate device is outlined in the table below:

Product	**UNIKO PointCloud™ Knee Instruments**	**Stryker ShapeMatch Cutting Guides**	**UNIKO PointCloud™ Knee Instruments**	**Conclusion**
510(k) number	K240327	K122053 – Primary Predicate	K193312 – Secondary Predicate	
Manufacturer	Unik Orthopedics Inc.	Stryker Corporation	Unik Orthopedics Inc.	
Product Code	MBH, JWH, OOG*	MBH, JWH, OOG*	MBH, OOG*	**Substantially Equivalent**
Regulation	21 CFR 888.3565 21 CFR 888.3560	21 CFR 888.3565** 21 CFR 888.3560**	21 CFR 888.3565*** 21 CFR 888.3560***	**SAME**
Intended Use / Indication				
Intended Use	Intended to be used as a Knee Arthroplasty Implantation System. Intended to be used to assist in the implantation of a specific knee arthroplasty device or a set of specific knee arthroplasty devices.	Intended to be used as a Knee Arthroplasty Implantation System. Intended to be used to assist in the implantation of a specific knee arthroplasty device or a set of specific knee arthroplasty devices.	Intended to be used as a Knee Arthroplasty Implantation System. Intended to be used to assist in the implantation of a specific knee arthroplasty device or a set of specific knee arthroplasty devices.	**SAME**
Indications for Use	The UNIKO PointCloud™ Knee Instruments are intended to be used as a surgical instrument to assist in the positioning of Total Knee Replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the Implant are identifiable on patient MRI scans. The UNIKO PointCloud™ Knee Instruments are compatible with the femoral and tibial components of the DJO Surgical	The ShapeMatch Cutting Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee arthroplasty components intraoperatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The ShapeMatch Cutting Guides are intended for use with the CR, PS, CS components of the Triathlon Knee	The UNIKO PointCloud™ Knee Instruments are intended to be used as a surgical instrument to assist in the positioning of Total Knee Replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the Implant are identifiable on patient imaging scans. The UNIKO PointCloud™ Knee Instruments are compatible with the femoral and tibial components of the DJO Surgical	**Substantially Equivalent** (The only differences are in the compatible knee implant systems)

Product	UNIKO PointCloud™ Knee Instruments	Stryker ShapeMatch Cutting Guides	UNIKO PointCloud™ Knee Instruments	
510(k) number	K240327	K122053 – Primary Predicate	K193312 – Secondary Predicate	
Manufacturer	Unik Orthopedics Inc.	Stryker Corporation	Unik Orthopedics Inc.	**Conclusion**
	EMPWR 3D Knee System and the Maxx Orthopedic Freedom Total Knee System. The Indications for Use of the DJO Surgical EMPWR 3D Knee System and the Maxx Orthopedic Freedom Total Knee System remain the same as those cleared in the manufacturer's clearance for the implant system.	System. The indications for use of the Triathlon Knee System when used with the ShapeMatch Cutting Guides are: *General Total Knee Arthroplasty (TKA) Indications:* -Painful, disabling joint disease of the knee resulting from; degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis. -Post-traumatic loss of knee joint configuration and function. -Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability. -Failed reconstruction procedures which did not involve the implantation of hardware on the condylar surfaces. *Additional Indications for Posterior Stabilized(PS):* -Ligamentous instability requiring implant bearing surface geometries with increased constraint. -Absent or non-functioning posterior cruciate ligament. -Severe anteroposterior instability of the knee joint.	EMPWR 3D Knee System. The Indications for Use of the DJO Surgical EMPWR 3D Knee System remain the same as those cleared in the manufacturer's clearance for the implant system.	

UNIKO
UNIK ORTHOPEDICS

UNIKO PointCloud™ Knee Instruments - Traditional 510(k) Submission

Product	**UNIKO PointCloud™ Knee Instruments**	**Stryker ShapeMatch Cutting Guides**	**UNIKO PointCloud™ Knee Instruments**	**Conclusion**
510(k) number	K240327	K122053 – Primary Predicate	K193312 – Secondary Predicate	
Manufacturer	Unik Orthopedics Inc.	Stryker Corporation	Unik Orthopedics Inc.	
Materials				
Femur Jig Guide	polyoxymethylene	polyoxymethylene	polyoxymethylene	**SAME**
Femur Cutslot	polyoxymethylene	polyoxymethylene	polyoxymethylene	**SAME**
Tibia Jig Guide	polyoxymethylene	polyoxymethylene	polyoxymethylene	**SAME**
Tibia Cutslot	polyoxymethylene	N/A – one piece	polyoxymethylene	**SAME**
Design				
Two part jig and cutslot	Yes	No, one piece jig and cut slot	Yes	**Substantially Equivalent**
Cutting Jigs are single use	Yes	Yes	Yes	**SAME**
Cutting Slots are single use	Yes	Yes	Yes	**SAME**
Cutting Guides are provided non-sterile	Yes	Yes	Yes	**SAME**
Technological Characteristics				
Software creates pre-op surgical plan based on MRI data	Yes	Yes	Yes	**SAME**
Surgeon approves plan	Yes	Yes	Yes	**SAME**
Patient specific cutting guides manufactured based on surgical plan	Yes	Yes	Yes	**SAME**
Guides for initial distal femoral and proximal tibial bone cuts	Yes	Yes	Yes	**SAME**
Implant manufacturer's implant specific guides used to complete implant specific cuts	Yes	Yes	Yes	**SAME**
Performance Testing				
Accuracy compared to Literature	At Least Equivalent to the Published Literature	Unknown	At Least Equivalent to the Published Literature	**Substantially Equivalent**
Accuracy compared to Predicate K193312	At Least Equivalent to Predicate	Unknown	N/A	**Substantially Equivalent**

Product	UNIKO PointCloud™ Knee Instruments	Stryker ShapeMatch Cutting Guides	UNIKO PointCloud™ Knee Instruments	
510(k) number	K240327	K122053 – Primary Predicate	K193312 – Secondary Predicate	
Manufacturer	Unik Orthopedics Inc.	Stryker Corporation	Unik Orthopedics Inc.	**Conclusion**
Meets the Acceptance Criteria of the Planned Surgery	Yes	N/A	Yes	**Substantially Equivalent**
Meets Biocompatibility according to ISO 10993	Yes	Yes	Yes	**SAME**

Performance Testing

A cadaver study was conducted to test the accuracy of the UNIKO PointCloud™ Knee Instruments cutting guides relative to the pre-operative plan, the previously cleared predicate and published literature. A total of 3 experienced orthopedic surgeons participated in the study. All 3 surgeons had prior experience using patient-specific instruments from different manufacturers. Each surgeon performed 3 TKAs on 3 different knees. This testing included measuring of the following angular measurements: varus/valgus, flexion/extension and internal/external rotation of the femur and varus/valgus and flexion/extension of the tibia. In all cases the accuracy of the measured angles was at least comparable to those of the UNIKO PointCloud™ Knee Instruments (K193312). These measures were also compared to published papers by (Matziolis - JBJS 2007: 89(2):236-243 and Ensini – CORR April 2007: 457:156-62) comparing data from a randomized study of computer-assisted and convention total knee arthroscopy. For all of the measured parameters, the results from the UNIKO PointCloud™ Knee Instruments were substantially better than the literature reported results from convention total knee surgery and comparable to those reported for the UNIKO PointCloud™ Knee Instruments.

The cadaver study also examined the measured accuracy of the resection thickness versus that specified in the pre-operative plan and demonstrated a comparable accuracy relative to the planned values. Overall, the fit of the cutting guides to the cadaver bone was considered to be excellent. All surgeons rated the pinning accuracy of the cutting guides as excellent meaning that the cut guides matched the bony landmarks consistently. The surgeons also evaluated the maximum extension, flexion and stability of the operated knees which demonstrated that the bone resections were consistent, and the values obtained were comparable to those of the predicate device.

The cadaver study demonstrated that the overall performance of the UNIKO PointCloud™ Knee Instruments performed favorably compared to the pre-operative plan and was at least comparable to the performance of the secondary predicate and to the accuracy reported for conventional surgical instruments in the literature.

Conclusion

In summary, the UNIKO PointCloud™ Knee Instruments is equivalent to the predicates, Stryker ShapeMatch Cutting Guides and the UNIKO PointCloud™ Knee Instruments cleared through K193312. It has the same intended use, and substantially equivalent Indications for Use, technological characteristics and operating principles, design, and materials to both predicates. The results of performance testing demonstrate that the UNIKO PointCloud™ Knee Instruments performed favorably compared to the pre-operative plan and was at least equivalent to the secondary predicate and to the accuracy reported for conventional surgical instruments in the literature. Furthermore, it did not raise any new questions of safety or effectiveness. The data presented supports a determination of Substantial Equivalence.