August 12, 2020

Unik Orthopedics, Inc.
Charlie Chi
CEO
1701 Fortune Drive, Unit E
San Jose, California 95131

Re: K193312
Trade/Device Name: UNIKO PointCloud™ Knee Instruments
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH
Additional product code: OOG
Dated: August 7, 2020
Received: August 7, 2020

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 (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,

Ting Song, Ph.D., R.A.C.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193312

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 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 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.

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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SECTION 6

510(k) SUMMARY

510(k) Number: K193312

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:	11 August 2020

Device Information:

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

Predicate Device:
The UNIKO PointCloud™ Knee Instruments are substantially equivalent in Intended Use, Indications for Use, Materials, Fundamental Scientific Technology and Performance to the following legally marketed devices in commercial distribution: Zimmer Patient Specific Instrument System 6.0 which was cleared by FDA through K140027 and the Stryker ShapeMatch Cutting Guide cleared through K122053

Device Description:
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 (the subject of this submission) 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 example AP, posterior condylar or transepicondylar (TEA) axis) 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 Knee Cutting Guides are patient specific and are intended as single use instruments compatible with TKA femoral and tibial components of the DJO Surgical EMPWR 3D Knee System. The Indications for Use of the DJO Surgical EMPWR 3D Knee System remain the same those cleared in the manufacturer's clearance for the implant system.

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 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 UNIKO PointCloud™ Knee Instruments are compatible with the femoral and tibial components of the DJO Surgical 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.

Substantial Equivalence:
Like the predicates, Zimmer Patient Specific Instruments System 6.0 and Stryker ShapeMatch Cutting Guides, the UNIKO PointCloud™ Knee Instruments are intended to be used as a Knee Arthroplasty Implantation System. A device accessory or set of device accessories that aids the surgeon in performing the implantation of the knee implant. Also, like the predicates, the UNIKO PointCloud™ Knee Instruments are indicated for use with femoral and tibial components of compatible FDA cleared total knee implant systems. Specifically, the UNIKO PointCloud™ Knee Instruments are cleared for use with the compatible femoral and tibia components of the FDA cleared uncemented DJO Surgical EMPWR 3D Knee System.

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

Product	**UNIKO PointCloud™ Knee Instruments**	**Zimmer Patient Specific Instruments System 6.0**	**Stryker ShapeMatch Cutting Guides**	
510(k) number	Subject Device	K140027	K122053	
Manufacturer	Unik Orthopedics Inc.	Materialise N.V. (Zimmer)	Stryker Corporation	**Conclusion**
Materials				
Femur Jig Guide	polyoxymethylene	polyamide	polyoxymethylene	**Substantially Equivalent**

Product	UNIKO PointCloud™ Knee Instruments	Zimmer Patient Specific Instruments System 6.0	Stryker ShapeMatch Cutting Guides	Conclusion
510(k) number	Subject Device	K140027	K122053	
Manufacturer	Unik Orthopedics Inc.	Materialise N.V. (Zimmer)	Stryker Corporation	
Femur Cutslot	polyoxymethylene	metal	polyoxymethylene	**Substantially Equivalent**
Tibia Jig Guide	polyoxymethylene	polyamide	polyoxymethylene	**Substantially Equivalent**
Tibia Cutslot	polyoxymethylene	metal	polyoxymethylene	**Substantially Equivalent**
Design				
Two part jig and cutslot	Yes	Yes	No One Piece Jig & Cutslot	**Substantially Equivalent**
Cutting Jigs are single use	Yes	Yes	Yes	**SAME**
Cutting Slots are single use	Yes	No	Yes	**Substantially Equivalent**
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

Biocompatibility testing demonstrates that the UNIKO PointCloud™ Knee Instruments, with limited exposure (up to 24 hours) of an external communicating device in direct contact to patient tissue, met the biocompatibility requirements per ISO 10993-1:2009.

Bench testing was performed on the UNIKO PointCloud™ Knee Instruments to verify and validate that the performance of the device meets the user needs and that the

device is substantially equivalent to the predicate when used with compatible femoral and tibial components of the DJO Surgical EMPWR 3D Knee System.

Testing consists of the following:

- Cutting Guide Leg Alignment Validation
- Jig Design Accuracy Validation
- Accuracy in Cadaver Testing Study
- Usability Validation

The results of this testing demonstrated that the UNIKO PointCloud™ Knee Instruments are capable of accurately producing the planned limb alignment from the Vault Software within the acceptance criteria of the study. For patients with severe varus/valgus deformities, the UNIKO PointCloud™ Knee Instruments could accommodate varus/valgus cut angles of up to +/- 10 Degrees for the femur and tibia. Testing also showed that given various levels of training of users in designing the jigs for femur and tibia, the standard deviation of errors for the varus/valgus angles, internal/external rotation, flexion/extension angles and anterior/posterior slope angles were within the acceptance criteria of the protocol.

Testing also conducted to quantify the accuracy of the UNIKO PointCloud™ Knee Instruments cutting guides relative to the pre-op surgical plan output by the Vault System Surgical Planning Software in a cadaveric model and to assess the accuracy in relation to literature values for conventional knee surgical instruments that are not patient specific. The difference between the measured resection thickness versus that specified in the pre-operative plan demonstrated a comparable accuracy relative to the planned values. Furthermore, the accuracy of the UNIKO cutting guides for use in total knee arthroplasty was at least comparable to the accuracy achieved using conventional jig-based instrumentation reported in the literature.

Usability testing of the UNIKO PointCloud™ Knee Instruments in a simulated clinical environment was conducted and indicated that all surgical teams were able to perform all steps outlined in the validation plan. The overall acceptance criteria of this usability study were met and surgeon satisfaction with the system exceeded the acceptance criteria of the study. The usability studies succeeded in validating that the UNIKO PointCloud™ Knee Instruments are a safe and effective means of performing TKA.

Conclusion

In summary, the UNIKO PointCloud™ Knee Instruments are equivalent to the predicates, Zimmer Patient Specific Instrument System 6.0 (K140027) and the Stryker ShapeMatch Cutting Guide (K122053), in the following ways: it has the same intended use, similar Indications for Use, the same or similar technological characteristics and operating principles, incorporates the same basic design and incorporates the same or similar materials. The results of performance testing demonstrate that the UNIKO PointCloud™ Knee Instruments performed substantially equivalent to the predicates and did not raise any new questions of safety and effectiveness. The data presented supports a determination of Substantial Equivalence.