September 9, 2020

Orthokey Italia S.r.l.
% Guido Bonapace
Regulatory Affair
Isemed srl
Via P. Togliatti, 19/X
Imola, 40026 Italy

Re: K192653
Trade/Device Name: Perseus
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 6, 2020
Received: August 10, 2020

Dear Guido Bonapace:

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K192653

Device Name
PERSEUS

Indications for Use *(Describe)*
PERSEUS is a computer-controlled system, intended to assist in distal femoral resection and tibial resection during Total Knee Arthroplasty, determining reference alignment axes in relation to anatomical and instrumentation structures during stereotaxic orthopaedic surgical procedures.

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 510(k) Summary is being submitted as required by **21 CFR 807.92.**

5.1 General Information

Submitter :

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Summary Prepared Date: September the 7th, 2020

5.2 Names

Device Name:	PERSEUS
Common Name:	Orthopedic Stereotaxic Instrument
Regulation Name:	Stereotaxic Instrument
Product Code:	OLO
Classification:	21 CFR 882.4560, Class II

5.3 Predicate Devices

The medical device PERSEUS is substantially equivalent to the following device legally marketed in the US:

Applicant	PREDICATE Device name	510(k) Number
OrthAlign Inc.	KneeAlign 2 System	K163379

Moreover, the following reference device has been considered:

Applicant	REFERENCE Device name	510(k) Number
Zimmer CAS	iASSIST™ Knee System	K141601

5.4 Device Description

PERSEUS is a computer assisted system, that helps surgeon in the positioning of implant components, during total knee implant surgical procedure, according to the conventional reference axes in relation to anatomical landmarks. Perseus System is configured to detect, measure, and display angular and positional measurement changes in a triaxial format.

The device assists the surgeon in:

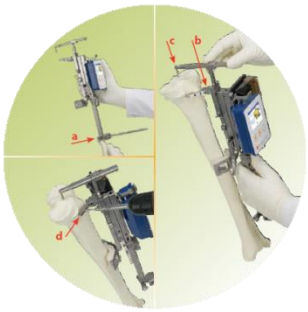
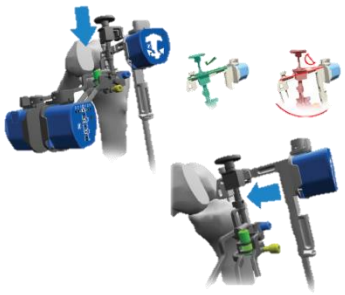
- Establishing the mechanical axis of the femur, determining the varus/valgus angle and the flexion/extension angle of the cutting block relative to the femur.
- Establishing the mechanical axis of the tibia, determining the varus/valgus angle and the posterior slope angle of the cutting block relative to the tibia.

Perseus system utilizes triaxial accelerometer and triaxial gyroscope to determine, through limb movement, reference axes of femur and tibia and relative orientation of distal femoral and tibial cutting guide with respect to frontal and sagittal planes of the limb.

5.5 Indications for Use

PERSEUS is a computer-controlled system, intended to assist in distal femoral resection and tibial resection during Total Knee Arthroplasty, by determining reference alignment axes in relation to anatomical and instrumentation structures during stereotaxic orthopedic surgical procedures.

5.6 Comparison with the predicate and the reference device

	Proposed Device	**Predicate Device**	**Reference Devices**
Product Name	**PERSEUS**	**KneeAlign 2 System**	**iASSIST Knee System**
Manufacturer	**Orthokey Italia S.r.l.**	**OrthAlign Inc.**	**Zimmer CAS**
510(K) No.		**K163379**	**K141601**
Classification Name	Orthopedic Stereotaxic Instrument	Orthopedic Stereotaxic Instrument	Orthopedic Stereotaxic Instrument
Figure			
Regulation Number	882.4560	882.4560	882.4560
Regulatory Class	II	II	II
Classification Product Code	OLO	OLO	OLO
Intended use			
Indications for use	PERSEUS is a computer-controlled system, intended to assist in distal femoral resection and tibial	The OrthAlign Plus®System is a computer-controlled system intended to assist the surgeon in determining reference	The iASSIST Knee System is a computer assisted stereotaxic surgical instrument system to assist the surgeon in the

	Proposed Device	Predicate Device	Reference Devices
Product Name	**PERSEUS**	**KneeAlign 2 System**	**iASSIST Knee System**
	resection during Total Knee Arthroplasty, by determining reference alignment axes in relation to anatomical and instrumentation structures during sterotactic orthopaedic surgical procedures.	alignment axes in relation to anatomical structures during stereotactic orthopedic surgical procedures. The KneeAlign system facilitates the accurate positioning of implants and instrumentation, relative to these alignment axes. Orthopedic surgical procedures include but are not limited to: Total Knee Arthroplasty Unicompartmental Knee Arthroplasty – Tibial Transverse Resection	positioning of orthopedic implant system components intra-operatively. It involves surgical instruments and position sensors to determine alignment axes in relation to anatomical landmarks and to precisely position alignment instruments and implant components relative to these axes. Example orthopedic surgical procedures include but are not limited to: Total Knee Arthroplasty.
Target population	Orthopedic surgical procedures include: Total knee arthroplasty	Orthopedic surgical procedures include but are not limited to: Total Knee Arthroplasty Uni-compartmental Knee Arthroplasty – Tibial Transverse Resection	Orthopedic surgical procedures include but are not limited to: Total knee arthroplasty
Anatomical site	knee	knee	Knee
Where used (hospital, home, ambulance, etc)	For professional use in operating room	For professional use in operating room	For professional use in operating room
Technology			
Energy used and/or delivered	• Navigation unit, reference sensor: DC battery power. • Instruments: manual position and orientation	• Navigation unit, reference sensor and laser module: DC battery power • Instruments: manual position and orientation	• Reference sensor: DC battery power. • Instruments: manual position and orientation
User Interface	Graphical user interface, on computer unit, outside sterile field.	Integrated graphical user interface, on an electronic unit that attaches to instrumentation.	Integrated graphical user interface, on an electronic unit that attaches to instrumentation.
Control Mechanism	Computer generation of positional information, using inertial sensors, microcontroller, digital signal processor and physical positions of registration instruments.	Computer generation of positional information, using inertial sensors, microcontroller, digital signal processor and physical positions of registration instruments.	Computer generation of positional information, using inertial sensors, microcontroller, digital signal processor and physical positions of registration instruments.
Operating Principles Registration of anatomy	Electronics attached to movable instruments, placed in specified procedural positions, for recording sensor data.	Electronics attached to movable instruments, placed in specified procedural positions, on or in contact with bony anatomy, for recording sensor data.	Electronics attached to movable instruments, placed in specified procedural positions, on or in contact with bony anatomy, for recording sensor data.
Measurement of change in angular orientations	• Computer displayed values based on internal calculations. • Accelerometer measurement of angular	• Computer displayed values based on internal calculation. • Accelerometer measurement of angular change in instrument positions.	• Computer displayed values based on internal calculation. • Accelerometer measurement of angular

	Proposed Device	Predicate Device	Reference Devices
Product Name	**PERSEUS**	**KneeAlign 2 System**	**iASSIST Knee System**
	change in instrument positions.		change in instrument positions.
Patient interface	Instrument fixation to bone with pins or screws. Instrument indications and engagement of bony anatomy via physical surface contact	Instrument fixation to bone with pins or screws. Instrument indications and engagement of bony anatomy via physical surface contact	Instrument fixation to bone with pins or screws. Instrument indications and engagement of bony anatomy via physical surface contact
Main System Components	• Non sterile reusable computer unit • Navigation and measurement software • Reusable instrument sets • Single-use sensor	• Single-use computer unit • Navigation and measurement software • Reusable instrument sets	• Non sterile reusable computer unit • Navigation and measurement software • Reusable instrument sets • Single-use sensor
Performance	HKA angle within 3°	HKA angle within 3°	HKA angle within 3°
Electrical Safety and EMC	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2
Materials	Stainless Steel grades common to orthopedic surgical instruments Polymer grades common to orthopedic surgical instruments Internal electronics	Stainless Steel grades common to orthopedic surgical instruments Polymer grades common to orthopedic surgical instruments Internal electronics	Stainless Steel grades common to orthopedic surgical instruments Polymer grades common to orthopedic surgical instruments Internal electronics
Biocompatibility	Per ISO 10993-1, External Communicating Device, Tissue/Bone/Dentin Communicating, with subsystems that have potential indirect contact for a limited contact duration (< 24 hours)	Per ISO 10993-1, External Communicating Device, Tissue/Bone/Dentin Communicating, with subsystems that have direct and potential indirect contact for a limited contact duration (< 24 hours)	Per ISO 10993-1, External Communicating Device, Tissue/Bone/Dentin Communicating, with subsystems that have direct and potential indirect contact for a limited contact duration (< 24 hours)
Compatibility with the environment and other devices	Specified storage and operating environments for typical transport and surgical environments.	Specified storage and operating environments for typical transport and surgical environments.	Specified storage and operating environments for typical transport and surgical environments.
Sterilization	• Navigation unit: EO sterilization. • Instruments: autoclave sterilization	• Navigation unit: EO sterilization. • Instruments: autoclave sterilization	• Navigation unit: EO sterilization. • Instruments: autoclave sterilization

The subject device PERSEUS fall under the same Regulation number, Regulatory Class and Product Code as the predicate device K163379 and the reference device K141601.
The indication for use of the subject device PERSEUS is similar to the one declared by the predicate device K163379 and the reference device K141601.
As per information provided in the table above, the technical and performance features of the proposed and predicate devices are similar or identical. In order to demonstrate the effective comparison related to clinical performance, biocompatibility, sterilization, packaging, shelf life, electrical and EMC safety, specific clinical evaluation and tests based on international standards have been performed.

In light of evidence listed in the table above, the proposed device PERSEUS can be considered substantially equivalent to the predicate device K163379 and the reference device K141601.

5.7 Performance Data

In order to demonstrate the accuracy and repeatability of the proposed device PERSEUS in terms of alignment of the resection level, with respect to mechanical axis, performance tests have been conducted.
Bench tests performance evaluation of Perseus has been done, verifying the orientation of femoral or tibial resections. Clinical evaluation has been done with the same performance requirement when possible or, in alternative, looking at final leg alignment with post-operative x-rays. The clinical evaluation has been prepared considering:

- **Bench testing**
- **Pre-clinical evaluation testing**
- **Aftermarket Clinical evaluation (Europe)**
- **Data generated from literature**

Bench testing have been conducted introducing controlled variables within an appropriate test setup throughout the subject device's operational range, to quantify the accuracy of the device. A set of bench tests have been designed in order to:

- Verify the measurement repeatability on a controlled setup, with different cursor positions of the jig
- Verify the error introduced by mispositioning of the ankle instrumentation
- Verify the repeatability of the measurement with different sensors
- Verify the repeatability of the measurement with different instrument positioning

Pre-clinical activities have been conducted to verify accuracy, repeatability and reproducibility in a simulated OR setup and to verify the consistency of the procedure when performed by different users with different level of experience.

Aftermarket clinical evaluation. Since Perseus is CE marked, aftermarket clinical evaluation has been done in Europe. Studies were conducted involving research centers in order to verify clinical results and performances of Perseus.
A study involved 3 cohorts of 10 patients each randomly selected, operated by the same surgical equipe, where perseus was used only for distal femoral resection. The cohorts were dividend in:

- EM Perseus; patients operated with Perseus
- EM Nav; patients operated with surgical navigation system,
- IM Conv; patients operated with conventional mechanical instrumentations.

Final limb alignment on frontal and lateral planes and blood loss have been measured postoperatively. Perseus has demonstrated to fulfil surgical goal of final HKA alignment within 3° of deviation and femoral distal resection within 2° of deviation, and a reduced blood loss, compared to conventional technique.
A second study only on femoral resection has been performed on a multicentric study involving two centers. The goal of the study was to verify blood loss and angular deviation of femoral distal resection on frontal and lateral planes, for two cohorts of 18 patients: 1 operated with the use of Perseus; 2 operated with conventional instrumentation. Perseus for the femoral resection has confirmed to satisfy the requirements of have a deviation < 2° in both frontal and lateral planes.
A third study was a single cohort evaluation, on 20 patients, of final limb alignment, blood loss and surgical time. Results show an average femoral resection alignment of 91±0.5° varus in frontal plane and 1.5±1.0° on sagittal plane.

Data on post-operative x-rays obtained from first 20 cases performed by the same user have been obtained. Results show an average post-operative deviation of HKA angle of 0.3±1.5°, femoral implant flexion of 0.8±0.8° and a tibial slope of 0.1±1.7°.
Data on post-operative x-rays obtained from 53 patients operated with Perseus and compared with 52 patients operated with conventional technique have been obtained. Results show and average post-operative deviation of HKA alignment of 0.7° with a range of 0-2°.

5.8 Conclusion

The comparison performed between the proposed device PERSEUS, the predicate device K163380 and the reference device K141601, is able to demonstrates that the device PERSEUS has similar technical features and clinical performance of the devices previously marketed in US. Particularly, even if the user interface is slightly different from the one proposed by the predicate device, this difference does not raise any new concern in terms of safety and effectiveness, as demonstrated through electrical safety, EMC, sterilization, packaging, shelf life and performance test reports.

In light of evidence summarized above and based on classification, intended use, technological characteristics, and performance data, the subject device PEPRSEUS may be found substantially equivalent to the predicate device KneeAlign 2 System (K163379) and the reference device iASSIST™ Knee System (K141601).