April 1, 2020

OrthoSensor, Inc.
Deborah Johnson
Director of Regulatory Affairs
1855 Griffin Road Suite A-310
Dania Beach, Florida 33004

Re: K193580
Trade/Device Name: VERASENSE for Zimmer Biomet Persona CR C-D/3-9 Left, VERASENSE for Zimmer Biomet Persona CR C-D/3-9 Right, VERASENSE for Zimmer Biomet Persona CR E-F/3-11 Left, VERASENSE for Zimmer Biomet Persona CR E-F/3-11 Right, VERASENSE for Zimmer Biomet Persona CR G-H/7-12 Left
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ONN
Dated: December 20, 2019
Received: December 23, 2019

Dear Deborah 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193580

Device Name
VERASENSE for Zimmer Biomet Persona

Indications for Use *(Describe)*
The VERASENSE for Zimmer Biomet Persona is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated.

For use as a tool to measure implant alignment and for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE for Zimmer Biomet Persona is sterile, for single patient use.

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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ORTHOSENSOR

Traditional 510(k) Summary

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

I. SUBMITTER

OrthoSensor, Inc.
1855 Griffin Road, Suite A-310
Dania Beach, FL 33004
Establishment Registration Number: 3008592715

Phone: (954) 577-7770
Fax: (954) 337-9222

Contact Person: Deborah Johnson, Director of Regulatory Affairs

Date Prepared: March 31, 2020

II. DEVICE

Name of Device: VERASENSE for Zimmer Biomet Persona
Common or Usual Name: Intraoperative Orthopedic Joint Assessment Aid
Classification Name: Stereotaxic instrument
Regulatory Class: II
Regulation Number: 21 CFR 882.4560
Product Code: ONN

III. PREDICATE DEVICE

Predicate Device - OrthAlign Plus System, K172462
Reference Device - VERASENSE for Zimmer Biomet Persona, K180459

IV. DEVICE DESCRIPTION

VERASENSE for Zimmer Biomet Persona provides a means to measure implant alignment and dynamically balance the knee during primary or revision Total Knee Arthroplasty (TKA).

The VERASENSE for Zimmer Biomet Persona consists of a knee sensor device and the following required accessories: LinkStation MINI or LinkStation MINI Evaluation Kit and VERASENSE Software Application (VSA). The required

accessories are intended to support the performance of the VERASENSE for Zimmer Biomet Persona parent device. Individual VERASENSE for Zimmer Biomet Persona devices are packaged sterile, for single patient use with a shim set for thickness adjustments. The required accessories are not packaged sterile and are reusable.

VERASENSE for Zimmer Biomet Persona devices are implant system specific due to variations in implant design and is compatible with the Zimmer Biomet Persona Knee System.

The VERASENSE for Zimmer Biomet Persona is an intelligent disposable tibial insert that measures dynamic loads in the medial and lateral compartments of the knee and angular velocity and acceleration for the alignment functionality. The data from the sensor is wirelessly transmitted to the LinkStation MINI or LinkStation MINI Evaluation Kit which runs the VSA and is located outside the sterile field in the operating room. The VSA provides the surgeon with a graphical and numerical presentation of the loads in both the medial and lateral compartments of the knee, center of load (COL) from the femoral to the tibial component in each of the medial and lateral compartments of the knee for reference only, static measurement of the coronal alignment of the tibial resection relative to the patient specific tibial reference axis defined by the system registered anatomical landmarks, and numerical value of the varus/valgus tibial mechanical alignment.

V. INDICATIONS FOR USE

The VERASENSE for Zimmer Biomet Persona is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated.

For use as a tool to measure implant alignment and for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE for Zimmer Biomet Persona is sterile, for single patient use.

VI. PRODUCT DESIGN CHANGES

The subject device is a modification to the previously cleared VERASENSE for Zimmer Biomet Persona (K180459). Changes from the reference device to the subject device:

1. Firmware version was updated to **enable the functionality of the IMU chip**. This change allows the VERASENSE Software Application VSA (Version 7) to process alignment information from the IMU chip.

2. Firmware version was updated to **change the power output** of the existing VERASENSE for Zimmer Biomet Persona device.

3. VERASENSE Software Application VSA (Version 7) accessory **algorithm was updated to include calculations for the tibial mechanical alignment**.

4. Labeling change - **Indications for use changed** from:

   > The VERASENSE is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated.
   >
   > For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE is sterile, for single patient use.

   to the following:

   > The VERASENSE for Zimmer Biomet Persona is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated.
   >
   > For use as a tool to measure tibial implant coronal alignment and for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The VERASENSE for Zimmer Biomet Persona is sterile, for single patient use.

   a. **Instructions for Use and the User Guide were updated** to include instructions for the alignment functionality.

5. There were no changes to hardware and the manufacturing process was equivalent to the reference device.

ORTHOSENSOR

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Technological Characteristic	Subject Device	Predicate Device K172462
Ligament Balancing	It has 3 load transducers per compartment that are used to calculate a composite joint load per compartment. Load transfer are derived from the measured loads.	Ligament balancing is achieved by measuring the angle and gap distances between the femur and proximal tibia and establishing a reference line to assist in setting the rotation of the femoral implant in primary or revision procedures.
Alignment Function	The varus/valgus angle of the resected tibia in the coronal plane is calculated using the established tibia reference frame and the patient tibial length measured by the surgeon and entered into the software application. The tibial mechanical alignment range is varus/valgus ±7° with an accuracy of ±3°. The VERASENSE for Zimmer Biomet Persona includes an accelerometer and gyroscope that make up the inertial measurement unit (IMU). The IMU is calibrated to removed fixed biases, scale errors, and misalignment errors in both the accelerometer, and gyroscope. The accelerometer provides the linear acceleration, while gyroscope provides the angular velocity, which are used to determine the frame of reference for the IMU. The VERASENSE for Zimmer Biomet Persona registers the first anatomical landmark, the center of the tibia, based on the placement of the VERASENSE for Zimmer Biomet device in the tibial tray implant. The IMU within the VERASENSE for Zimmer Biomet Persona is centered with respect to the implant tibial tray, with a specific offset value for each size and side of the device. The second anatomical landmark, the lateral center of the heel's calcaneus, is registered when the surgeon takes the leg through a pivot motion with the heel stabilized, while the hip and the pelvis are stable through the patient position.	The mechanical alignment is defined as the axis from the center of the femoral head to the intercondylar notch. This axis extends further down from the center of the proximal tibia to the center of the ankle. The main observed difference is the algorithm used by the software and the mechanical measurements based on the sensor versus the femoral and tibial jigs used by OrthAlign. The OrthAlign also can be used for hip and knee arthroplasty, while VERASENSE for Zimmer Biomet Persona is only used for knee arthroplasty.

ORTHOSENSOR

Technological Characteristic	Subject Device	Predicate Device K172462
Communication	**Sensor:** Bluetooth 4.2 compatible **LinkStation MINI/LinkStation MINI Evaluation Kit:** Bluetooth 4.2 compatible, WIFI	Bluetooth
Electrical details (power, outlets, voltage etc.)	**Sensor:** Internally powered (3.1V DC) **LinkStation MINI /LinkStation MINI Evaluation Kit:** AC Power **Protection against electrical Shock:** Type BF Applied **Electromagnetic Interference (EMI):** will tolerate typical levels of electromagnetic interface **Electrostatic Discharge (EDS)** will tolerate exposure to 8kV contact discharge and 8 kV air discharge. **Display Unit Protection Against Electrical Shock** Class I (65W universal 3-pin jack, 100-240V, 1.5A, 50-60Hz) **Transceiver Unit Protection Against Electrical Shock** Class II USB powered and intended to be connected to the USB port of the LinkStation MINI display unit (5 V dc)	**Navigation unit, reference, sensor, and laser module**: DC battery powered **Protection against electrical Shock:** Type BF Applied. **Electromagnetic Interference (EMI):** Unknown **Electrostatic Discharge (EDS)** Unknown
Software	The VERASENSE Software Application calculates force vectors and positional data, display both numerically and pictorially load data versus position, according to the description and specifications. For alignment, the VSA displays the tibial varus/valgus alignment angle numerically using tibial length, positional data, angular velocity. **User Interface:** Accessory with tablet computer with a graphical user interface **Operating System Compatibility (display Unit):** Microsoft Windows 10	**User Interface:** Integrated graphical user interface, on an electronic unit that attaches to instrumentation. **Operating system:** unknown

Technological Characteristic	Subject Device	Predicate Device K172462
Packaging	**Sensor:** double pouched, sterile **Accessories:** LinkStation MINI - Wood box LinkStation MINI Evaluation Kit – Waterproof plastic case	Sensor and accessories are packaged sterile
Ingress of Liquids	**Sensor:** Rated IPX4 **Display Unit:** Rated IP54	unknown
Sterilization	**Sensor:** Ethylene Oxide 10^{-6} SAL **LinkStation MINI/LinkStation MINI Evaluation Kit:** Non-Sterile	**Navigation Unit:** EO Sterilization **Instruments:** Autoclave Sterilization

The technological characteristics are the same with the exception of alignment and ligament balancing calculation methods.

VIII. PERFORMANCE DATA

In order to review the different characteristics and support of the substantial equivalence determination the following performance verification studies were performed:

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The software accessory for this device was considered as a "minor" level of concern, since the VERASENSE Software Application reports real time the amount of applied force, COL location (for reference only), and tibial varus/valgus angle from the VERASENSE for Zimmer Biomet Persona. The VERASENSE Software Application does not directly drive a decision regarding treatment or therapy.

Performance Testing Bench

In order to test the Alignment function calculation (technological difference and new design change), the following studies were performed:

- Benchtop Design, Cadaver Design, Benchtop Sensitivity analysis, Usability, Software Verification. The method for calculating alignment was verified through sensitivity analysis and a mathematical simulation.
- Ligament balancing calculation method was previously cleared per VERASENSE for Zimmer Biomet persona (K180459) reference device

Performance Testing Clinical

This submission does not include any clinical testing. We determined that no such testing was required to demonstrate substantial equivalence.

Performance Testing Animal

This submission does not include any animal performance testing. We determined that no such testing was required to demonstrate substantial equivalence.

IX. CONCLUSIONS

Performance studies demonstrated the product meets established acceptance criteria. Failure mode and effects analysis also demonstrated that all risks related to the different characteristics have been reduced as far as possible. The different technological characteristics do not raise different questions in regard to safety and effectiveness of the product. Thus, the modifications are substantially equivalent to the predicate device.