June 7, 2018

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

Re: K180459
Trade/Device Name: VERASENSE for Zimmer Biomet Persona
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ONN
Dated: May 16, 2018
Received: May 17, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180459

Device Name
VERASENSE for Zimmer Biomet Persona

Indications for Use *(Describe)*
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.

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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K180459

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.
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Establishment Registration Number: 3008592715

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Contact Person: Deborah Johnson, Senior Manager Regulatory Affairs

Date Prepared: May 15, 2018

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

VERASENSE Knee System, K150372

IV. DEVICE DESCRIPTION

VERASENSE provides a means to dynamically balance the knee during primary or revision Total Knee Arthroplasty (TKA).

The VERASENSE consists of a knee sensor device and the following required accessories: LinkStation MINI or LinkStation Evaluation Kit and VERASENSE Software Application (VSA). The required accessories are intended to support the performance of the VERASENSE parent device. The LinkStation MINI / LinkStation MINI Evaluation Kit is capable of running the VSA and communicating wirelessly with the VERASENSE from outside the sterile field in the operating room. Individual VERASENSE 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.

The VERASENSE device is an intelligent disposable tibial insert that measures dynamic loads in the medial and lateral compartments of the knee and wirelessly transmits the measured load data to the LinkStation MINI or LinkStation MINI Evaluation Kit. The VSA provides the surgeon with a graphical and numerical presentation of the loads in both the medial and lateral compartments of the knee. The VSA also provides location of the center of load (COL) from the femoral to the tibial component in each of the medial and lateral compartments for reference only.

VERASENSE devices are implant system specific due to variations in implant design. VERASENSE is compatible with the following implant systems:

- VERASENSE for Biomet Vanguard
- VERASENSE for Stryker Triathlon
- VERASENSE for Zimmer NexGen
- VERASENSE for Smith & Nephew Legion
- VERASENSE for Smith & Nephew Journey II
- VERASENSE for Zimmer Biomet Persona

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

At a high level, the subject and predicate devices are based on the following same technological elements:

- Capacitive sensors on the device measure the pressure exerted by the femoral component of the implant on the sensor.
- Required accessories intended to support the performance of the VERASENSE parent device are the LinkStation MINI or LinkStation MINI Evaluation Kit and VERASENSE Software Application (VSA)
- Patient contacting material of the top and bottom housings

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

- the geometry / dimensions of the Zimmer Biomet Persona implant system
- Articular surface is on shims, detached from the electronics
- Electronics module is reversible
- Patient contacting shim material changed to PolyEtherEtherKetone (PEEK) and stainless steel
- Sensor wireless communication frequency changed to 2402 – 2480 MHz Bluetooth
- New wireless connection mode for the LinkStation MINI / LinkStation MINI Evaluation Kit via tablet component integrated Bluetooth
- New version of the VSA with the addition of the VERASENSE for Zimmer Biomet Persona to the scope of the software application
- Updated labeling to include compatibility with VERASENSE for Zimmer Biomet Persona variant and instructions for new wireless connection mode

	Predicate Device K150372	**Subject Device**
Classification	21 CFR 882.4560	21 CFR 882.4560
Product Code	ONN	ONN
Indications for Use	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.	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.
Environment	Hospital	Hospital
VERASENSE (sensor)		
Operating Principle	Capacitive sensors on the device measure the pressure exerted by the femoral component of the implant on the sensor.	Capacitive sensors on the device measure the pressure exerted by the femoral component of the implant on the sensor.
Power Requirements	Internally powered Two 1.55V, 27mAh Silver Oxide batteries (in series)	Internally powered Two 3V, 30mAh Lithium batteries (in parallel)

		Predicate Device K150372	Subject Device
Form of Wireless technology		Radio Frequency	Radio Frequency
RF Frequencies	VERASENSE for Stryker Triathlon	402.0 – 405.0 MHz	
	VERASENSE for Biomet Vanguard	404.3 MHz	
	VERASENSE for Zimmer NexGen		
	VERASENSE for Smith & Nephew Legion		
	VERASENSE for Smith & Nephew Journey II		
	VERASENSE for Zimmer Biomet Persona		2402 – 2480 MHz Bluetooth
Range		2 m	2 m
Packaging		Sterile, Double Tyvek /Film pouches, chipboard box	Sterile, Double Tyvek /Film pouches, chipboard box
Sterilization Method (sensor only)		Ethylene Oxide 10^{-6} SAL	Ethylene Oxide 10^{-6} SAL
Materials (patient contacting)	Top housing	Colored Polycarbonate Resin	Colorless Polycarbonate Resin
	Bottom housing	Colorless Polycarbonate Resin	Colorless Polycarbonate Resin
	Adhesive between top and bottom housing	Loctite	Loctite
	Shims	Colored Polycarbonate Resin	10, 11, 12, 13 mm VITREX PolyEtherEtherKetone (PEEK) 381G & stainless steel metal plates
			14 and 16 mm VITREX PolyEtherEtherKetone (PEEK) 381G
Shelf Life		24 months	3 months

	Predicate Device K150372		Subject Device	
Required Accessories (intended to support the performance of the VERASENSE parent device)				
VERASENSE Software Application (VSA)				
	VSA for Mac OX	**VSA for Microsoft Windows**	**VSA for Microsoft Windows**	
Operating Principle	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.	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.	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.	
Operating System Compatibility	Mac OSX	Microsoft Windows	Microsoft Windows	
VSA version number(s)	3.7 - 3.9.4.2	4.0.31.0 – 5.0.0.0	5.1.0.17	
LinkStation				
	LinkStation		**LinkStation MINI**	**LinkStation MINI Evaluation Kit**
Operating Principle	Transceiver is connected to LinkStation via a USB cable. Data from the VERASENSE is wirelessly received by the transceiver at a frequency of 401.05-405.55 MHz. The transceiver processes Gaussian Frequency-Shift Keying (GFSK) modulated data		The transceiver component of the LinkStation MINI/LinkStation MINI Evaluation Kit can receive and process simultaneously 2 channels and the carrier frequency band for the wireless communication is 401.05 – 405.55 MHz. The integrated Bluetooth transceiver in the tablet computer component of the LinkStation MINI/LinkStation MINI Evaluation Kit carrier frequency band for the wireless communication is 2402 – 2480 MHz Bluetooth 4.0 compatible. The transceivers processes Gaussian Frequency-Shift Keying (GFSK) modulated data.	The transceiver component of the LinkStation MINI/LinkStation MINI Evaluation Kit can receive and process simultaneously 2 channels and the carrier frequency band for the wireless communication is 401.05 – 405.55 MHz. The integrated Bluetooth transceiver in the tablet computer component of the LinkStation MINI/LinkStation MINI Evaluation Kit carrier frequency band for the wireless communication is 2402 – 2480 MHz Bluetooth 4.0 compatible. The transceivers processes Gaussian Frequency-Shift Keying (GFSK) modulated data.

		Predicate Device K150372	Subject Device	
Sensor Compatibility		VERASENSE for Stryker Triathlon	VERASENSE for Stryker Triathlon	VERASENSE for Stryker Triathlon
		VERASENSE for Biomet Vanguard	VERASENSE for Biomet Vanguard	VERASENSE for Biomet Vanguard
		VERASENSE for Zimmer NexGen	VERASENSE for Zimmer NexGen	VERASENSE for Zimmer NexGen
		VERASENSE for Smith & Nephew Legion	VERASENSE for Smith & Nephew Legion	VERASENSE for Smith & Nephew Legion
		VERASENSE for Smith & Nephew Journey II	VERASENSE for Smith & Nephew Journey II	VERASENSE for Smith & Nephew Journey II
			VERASENSE for Zimmer Biomet Persona	VERASENSE for Zimmer Biomet Persona
Display Unit		Apple iMac 27”	Tablet PC 12.5”	Tablet PC 12.5”
	Display Unit Connection Modes	WIFI connectivity, Bluetooth connectivity, USB ports, Ethernet, Thunderbolt, and FireWire	WIFI connectivity, Bluetooth connectivity, and a USB port	WIFI connectivity, Bluetooth connectivity, and a USB port
	Display Unit Power Requirements	310W universal 3-pin jack, 100-240V, 50-60Hz	65W universal 3-pin jack, 100-240V, 1.5A, 50-60Hz	65W universal 3-pin jack, 100-240V, 1.5A, 50-60Hz
	Display Unit Operating System	Mac OSX	Windows 10	Windows 10
Stand Component		Ergotron Neo-Flex Stand	Roll Stand	Tablet Kickstand
Magnet		Neodymium magnet with a magnet to steel disc pull of greater than 2.75 lbs	Neodymium magnet with a magnet to steel disc pull of greater than 2.75 lbs	Neodymium magnet with a magnet to steel disc pull of greater than 2.75 lbs
Transceiver Component	**Mount**	Mounted on roll stand	Mounted on roll stand	Mounted on tripod
	Power requirements	USB powered and intended to be connected to the USB port of the LinkStation MINI display unit (5 V dc)	USB powered and intended to be connected to the USB port of the LinkStation MINI display unit (5 V dc)	USB powered and intended to be connected to the USB port of the LinkStation MINI display unit (5 V dc)
	Form of Wireless technology	Radio Frequency	Radio Frequency	Radio Frequency
	RF Frequencies	401.05 – 405.55MHz	401.05 – 405.55MHz	401.05 – 405.55MHz
	Range	2 m	2 m	2 m
Sterilization Method		N/A. Supplied non-sterile.	N/A. Supplied non-sterile.	N/A. Supplied non-sterile.
Patient Contacting Materials		None	None	None
Shelf Life		5 years	5 years	5 years

		Predicate Device K150372	Subject Device
Sensor and Required Accessories			
Electrical Safety*		AAMI ANSI ES60601-1:2005	AAMI ANSI ES60601-1:2005
Electromagnetic Compatibility (EMC)*		IEC 60601-1-2:2007AC:2010	IEC 60601-1-2:2007AC:2010
Performance Specifications	**Operating Range**	5 - 40 lbf	5 - 40 lbf
	Load Accuracy	±3.5 lbf	±3.5 lbf
	Load Values Displayed for Reference only	41-70 lbf	41-70 lbf
	Maximum Safe Load	70 lbf	70 lbf

*** when VERASENSE and accessories tested together**

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the VERASENSE for Zimmer Biomet Persona was conducted in accordance with Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff, Issued 06-16-2016. The biocompatibility tests conducted were:

- Cytotoxicity
- Sensitization
- Irritation
- Acute systemic toxicity
- Material mediated pyrogenicity

The VERASENSE for Zimmer Biomet Persona is an implant device with limited duration contact (<24 hours) with tissue/bone.

Based on the results of the biocompatibility testing performed on the final VERASENSE for Zimmer Biomet Persona, in addition to the biocompatibility

testing results of the raw materials, the VERASENSE for Zimmer Biomet Persona meets the requirements outlined in EN ISO 10993-1:2009/AC:2010.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the VERASENSE for Zimmer Biomet Persona and required accessories. The subject device and required accessories comply with the IEC 60601-1 standard for electrical safety and the IEC 60601-1-2 standard for EMC.

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 and COL location (for reference only) from the VERASENSE device. The VERASENSE Software Application does not directly drive a decision regarding treatment or therapy.

Performance Testing Bench

The safety performance of the VERASENSE for Zimmer Biomet Persona has been verified according to OrthoSensor, Inc's procedures for product design and development to ensure that it meets its intended use, including:

- Usability
- Sterilization
- Packaging Integrity
- Shelf life
- Biocompatibility Assessment
- Electrical Safety Testing IEC 60601-1
- Electromagnetic Compatibility (EMC) IEC 60601-1-2
- Design Verification and Validation
- Software Verification and Validation

Performance Testing Animal

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

Performance Testing Clinical

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

VIII. CONCLUSIONS

The subject device VERASENSE for Zimmer Biomet Persona and required accessories have the same intended use, indications for use, environment, sterilization method, operating principle, packaging, electrical safety, and electromagnetic compatibility as the predicate device VERASENSE and required accessories. The differences in dimensions, wireless communications, materials, and shelf life have been identified and we determined that they have no impact on safety and effectiveness. Thus, the modifications are substantially equivalent to the previously cleared VERASENSE and required accessories.