April 12, 2020

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

Re: K200665
Trade/Device Name: VERASENSE for Stryker Triathlon
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ONN
Dated: March 11, 2020
Received: March 13, 2020

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, MPH
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)*
K200665

Device Name
VERASENSE for Stryker Triathlon

Indications for Use *(Describe)*
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.

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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Special 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 11, 2020

II. DEVICE

Name of Device: VERASENSE for Stryker Triathlon
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

Primary: VERASENSE for Zimmer Biomet Persona, K180459
Reference: VERASENSE Knee System, K150372

IV. DEVICE DESCRIPTION

The VERASENSE device is an intelligent disposable tibial insert trial that measures dynamic loads in the medical and lateral compartments of the knee and wirelessly transmits the measured load data to the LinkStation MINI and LinkStation MINI Evaluation Kit with VERASENSE Software Application (VSA). The VSA provides the surgeon with a graphical and numerical presentation of the load magnitude and center of load (COL) location (weighted average) of the femoral to the tibial component in each of the medial and lateral compartments of the knee for reference only. Individual VERASENSE devices are packaged sterile, for single patient use with a shim set for thickness adjustments.

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

- Biomet Vanguard
- Stryker Triathlon
- Zimmer NexGen
- Smith & Nephew Journey II
- Smith & Nephew Legion
- 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 in the device measure the pressure exerted by the implant component on the sensor.
- Required hardware and software application accessories intended to support the performance of the parent device are the LinkStation MINI or LinkStation MINI Evaluation Kit and VERASENSE Software Application (VSA)
- Patient contacting materials for the bottom housing

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

- Labeling
- Dimensions (same as reference device)
- Battery (same as reference device)
- Patient contacting materials (same as reference device)
- Firmware version
- Software application accessory version

The subject and reference devices are based on the following same technological elements:

- Capacitive sensors in the device measure the pressure exerted by the implant component on the sensor.
- Required hardware and software application accessories intended to support the performance of the parent device are the LinkStation MINI or LinkStation MINI Evaluation Kit and VERASENSE Software Application (VSA)
- Patient contacting materials for top and bottom housing components and adhesives
- Patient contacting materials for shim assemblies

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

- Labeling
- Firmware version
- Software application accessory version

	Predicate Device K180459	Subject Device	Substantially Equivalent or Difference
Sensor and required accessories			
Classification	21 CFR 882.4560	21 CFR 882.4560	N/A
Product Code	ONN	ONN	N/A
Intended Use	VERASENSE provides a means for orthopedic surgeons to dynamically balance the knee during primary or revision Total Knee Arthroplasty (TKA).	VERASENSE provides a means for orthopedic surgeons to dynamically balance the knee during primary or revision Total Knee Arthroplasty (TKA).	Substantially Equivalent
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.	Substantially Equivalent

	Predicate Device K180459	Subject Device	Substantially Equivalent or Difference
Environment	Hospital	Hospital	Substantially Equivalent
Electrical Safety*	IEC 60601-1	IEC 60601-1	Substantially Equivalent
Electromagnetic Compatibility (EMC)*	IEC 60601-1-2	IEC 60601-1-2	Substantially Equivalent
Usability*	IEC 62366	IEC 62366	Substantially Equivalent
Labeling	VERASENSE for Zimmer Biomet Persona product label, VERASENSE knee sensor IFU, and VERASENSE knee sensor and accessories user guide.	VERASENSE for Stryker Triathlon product label, VERASENSE knee sensor IFU, and VERASENSE knee sensor and accessories user guide.	**Technological Difference #1**

*when sensor and accessories tested together

			Predicate Device K180459	Subject Device	Substantially Equivalent or Difference
SENSOR (parent device)					
Mechanical	**Dimensions**		VERASENSE for Zimmer Biomet Persona sensor is equal to the dimensions of the implant trial or final liner ± 0.50 mm under all operating conditions	VERASENSE for Stryker Triathlon sensor is equal to the dimensions of the implant trial or final liner ± 0.50 mm under all operating conditions	**Technological Difference #2** Subject device housing dimensions are the same as the reference device.
Functional	**Operating Principle**		Capacitive sensors on the device measure the pressure exerted by the femoral component of the implant on the sensor (two compartments, three pressure sensors in each compartment)	Capacitive sensors on the device measure the pressure exerted by the femoral component of the implant on the sensor (two compartments, three pressure sensors in each compartment)	Substantially Equivalent
	Applied Force of Load Sensing	**Load Range and Accuracy**	5-40 lbf ≤ 3.5 lbf	5-40 lbf ≤ 3.5 lbf	Substantially Equivalent
			41-70 lbf for reference only	41-70 lbf for reference only	Substantially Equivalent
		Maximum Safe Load	70 lbf	70 lbf	Substantially Equivalent
	Center of Load (COL) Location		For Reference Only	For Reference Only	Substantially Equivalent
	Communication		Transmission of data from sensor to the LinkStation MINI or LinkStation MINI Evaluation Kit.	Transmission of data from sensor to the LinkStation MINI or LinkStation MINI Evaluation Kit.	Substantially Equivalent
	Battery		40 min	40 min	Substantially Equivalent

			Predicate Device K180459	Subject Device	Substantially Equivalent or Difference
Electrical	Battery	Type	Lithium Ion coin cell	Silver Oxide coin cell	**Technological Difference #3** Subject device battery is the same battery as the reference device
		Operating Voltage and current	3.1 V DC 30 mAh	1.55V 27 mAh	
		Connection Type	Two batteries in parallel	Two batteries in series	
	IEC 60601-1 Medical Electrical Equipment Classification	Protection Against Electric Shock	Internally powered	Internally powered	Substantially Equivalent
		Installation and Use	Hand held	Hand held	Substantially Equivalent
		Applied Part	Type BF	Type BF	Substantially Equivalent
		Protection against harmful ingress of water or particulate matter	IPX4	IPX4	Substantially Equivalent
		Mode of Operation	Continuous	Continuous	Substantially Equivalent
		Suitability in an oxygen rich environment	No	No	Substantially Equivalent
	Wireless Communication	Technology	Radio Frequency	Radio Frequency	Substantially Equivalent
		Frequency Band	2402 – 2480 MHz	2402 – 2480 MHz	Substantially Equivalent
		Communication Protocol	Bluetooth Low Energy (BLE) 4.2	Bluetooth Low Energy (BLE) 4.2	Substantially Equivalent
		Range	2 m	2 m	Substantially Equivalent
	Electromagnetic Interference (EMI)		Sensor will tolerate typical levels of electromagnetic interface experience in the operating room environment.	Sensor will tolerate typical levels of electromagnetic interface experience in the operating room environment.	Substantially Equivalent
	Electrostatic Discharge (ESD)		8kV contact discharge 15 kV air discharge	8kV contact discharge 15 kV air discharge	Substantially Equivalent

			Predicate Device K180459	Subject Device	Substantially Equivalent or Difference
Environmental	Operating Conditions	Storage temperature	15 - 37 °C	15 - 37 °C	Substantially Equivalent
		Relative humidity	30 - 100% submersion	30 - 100% submersion	Substantially Equivalent
	Storage Conditions	Storage temperature	0 - 50 °C	0 - 50 °C	Substantially Equivalent
		Relative humidity	10 - 80% non-condensing	10 - 80% non-condensing	Substantially Equivalent
		Atmospheric pressure	36 – 106 kPa	36 – 106 kPa	Substantially Equivalent
Materials (patient contacting)	**Type of Contact**		with tissue/bone	with tissue/bone	Substantially Equivalent
	Duration of Contact		limited duration contact (<24 hours)	limited duration contact (<24 hours)	Substantially Equivalent
	Housing	Top	Colorless Polycarbonate Resin	Colored Polycarbonate Resin (Size 2 black, Size 3 brown, Size 4 green, Size 5 blue, Size 6 yellow, Size 7 burnt orange)	**Technological Difference #4** Subject device materials are the same as the predicate and reference devices
		Bottom	Colorless Polycarbonate Resin	Colorless Polycarbonate Resin	
	Adhesive	Between top and bottom housing	Loctite 3936	Loctite 3936	
		For vent hole	Loctite 3936	Loctite 3936	
	Shims		10, 11, 12, 13 mm VITREX PolyEtherEtherKetone (PEEK) 381G & stainless-steel metal plates	Sizes 9, 10, 11, 12, 13, 16 mm Colored Polycarbonate Resin (Size 2 black, Size 3 brown, Size 4 green, Size 5 blue, Size 6 yellow, Size 7 burnt orange)	
			14 and 16 mm VITREX PolyEtherEtherKetone (PEEK) 381G		
Sterilization Method			Ethylene Oxide 10^{-6} SAL	Ethylene Oxide 10^{-6} SAL	Substantially Equivalent
Shelf Life			24 months	24 months	Substantially Equivalent
Packaging			Sterile, Double Tyvek /Film pouches, chipboard box	Sterile, Double Tyvek /Film pouches, chipboard box	Substantially Equivalent
Firmware version			VERASENSE knee sensor firmware version 2.2.2 which includes communication modes and calibration coefficient.	VERASENSE knee sensor firmware version 3.1.24 which includes communication modes and calibration coefficient.	**Technological Difference #5**

	Predicate Device K180459	Subject Device	Substantially Equivalent or Difference
Required Accessories (Intended to support the performance of the VERASENSE sensor parent device)			
SOFTWARE ACCESSORY			
Operating Principle	The VERASENSE Software Application (VSA) calculates force vectors and positional data, display both numerically and pictorially load data versus position.	The VERASENSE Software Application (VSA) calculates force vectors and positional data, display both numerically and pictorially load data versus position.	Substantially Equivalent
Programming Language	C#	C#	Substantially Equivalent
Operating System Compatibility	Microsoft Windows	Microsoft Windows	Substantially Equivalent
Level of Concern	Minor	Minor	Substantially Equivalent
Version	≥5.1.0.17	≥5.3.0.64	**Technological Difference #6**
HARDWARE ACCESSORY			
Operating Principle	The LinkStation MINI and LinkStation MINI Evaluation Kit receives and processes process Gaussian Frequency-Shift Keying (GFSK) modulated data from the sensors. The LinkStation MINI can be transported from storage location to and from placement positioning of the system within the operating room without causing delay to surgical flow. The LinkStation MINI Evaluation Kit can be transported from case to case and be robust for assembly and break down in surgical environments with repeated use.	The LinkStation MINI and LinkStation MINI Evaluation Kit receives and processes process Gaussian Frequency-Shift Keying (GFSK) modulated data from the sensors. The LinkStation MINI can be transported from storage location to and from placement positioning of the system within the operating room without causing delay to surgical flow. The LinkStation MINI Evaluation Kit can be transported from case to case and be robust for assembly and break down in surgical environments with repeated use.	Substantially Equivalent
Stand Component	Roll Stand with utility basket and lockable casters / Tablet Kickstand	Roll Stand with utility basket and lockable casters / Tablet Kickstand	Substantially Equivalent
Magnet Component	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	Substantially Equivalent

Display Unit Mount			Connects to stand with tilt and rotation	Kickstand that holds tablet on tabletop	Connects to stand with tilt and rotation	Kickstand that holds tablet on tabletop	Substantially Equivalent
			Predicate Device K180459		**Subject Device**		**Substantially Equivalent or Difference**
USB Cable			USB 2.0 down angle A male to up angle MINI-B male 10" (25.4cm)	USB 2.0 down angle A male to up angle MINI-B male 10" (25.4cm)	USB 2.0 down angle A male to up angle MINI-B male 10" (25.4cm)	USB 2.0 down angle A male to up angle MINI-B male 10" (25.4cm)	Substantially Equivalent
Environmental	**Operating Conditions**	Storage temperature	-10 - 60 °C		-10 - 60 °C		Substantially Equivalent
		Relative humidity	5 - 95% non-condensing		5 - 95% non-condensing		Substantially Equivalent
	Storage Conditions	Storage temperature	0 - 50 °C		0 - 50 °C		Substantially Equivalent
		Relative humidity	5 - 95% non-condensing		5 - 95% non-condensing		Substantially Equivalent
play Unit	**Type**		Tablet PC 12.5 in (31.8 cm) diagonal touchscreen 256 color display		Tablet PC 12.5 in (31.8 cm) diagonal touchscreen 256 color display		Substantially Equivalent
	Weight		5.5 lbs (2.5 kg)		5.5 lbs (2.5 kg)		Substantially Equivalent
	Camera		2.0-megapixel resolution		2.0-megapixel resolution		Substantially Equivalent
	Electrical	**Battery**	Lithium Ion		Lithium Ion		Substantially Equivalent
		Power Supply	19V with AC Adapter		19V with AC Adapter		Substantially Equivalent
		USB Port	3.0		3.0		Substantially Equivalent
		IEC 60601-1 Medical Electrical Equipment Classification **Protection Against Electric Shock**	Class I		Class I		Substantially Equivalent
		Installation and Use	Transportable		Transportable		Substantially Equivalent
		Applied Part	No Applied Parts (does contact patient)		No Applied Parts (does contact patient)		Substantially Equivalent
		Protection against harmful ingress of water or particulate matter	IP54		IP54		Substantially Equivalent
		Mode of Operation	Continuous		Continuous		Substantially Equivalent
		Suitability in an oxygen rich environment	No		No		Substantially Equivalent
		W Technology	Radio Frequency		Radio Frequency		Substantially Equivalent

			Integrated Communications	Wireless-AC 8260 Wi-Fi plus Bluetooth 4.2	Wireless-AC 8260 Wi-Fi plus Bluetooth 4.2	Substantially Equivalent

				Predicate Device K180459		Subject Device		Substantially Equivalent or Difference
Transceiver Mount				Mounted on roll stand	Mounted on tripod	Mounted on roll stand	Mounted on tripod	Substantially Equivalent
Transceiver Component	**Electrical**	**Power**		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)		Substantially Equivalent
		IEC 60601-1 Medical Electrical Equipment	Protection Against Electric Shock	Class II		Class II		Substantially Equivalent
			Installation and Use	Portable		Portable		Substantially Equivalent
			Applied Part	No Applied Parts (does not contact patient)		No Applied Parts (does not contact patient)		Substantially Equivalent
			Protection against harmful ingress of water or particulate matter	Not ingress protected		Not ingress protected		Substantially Equivalent
			Mode of Operation	Continuous		Continuous		Substantially Equivalent
			Suitability in an oxygen rich environment	No		No		Substantially Equivalent
		Wireless	**Technology**	Radio Frequency		Radio Frequency		Substantially Equivalent
			Frequency Band	401.05 – 405.55MHz		401.05 – 405.55MHz		Substantially Equivalent
			Communication Protocol	Proprietary		Proprietary		Substantially Equivalent
Sterilization Method				N/A Supplied non-sterile		N/A Supplied non-sterile		Substantially Equivalent
Materials (Patient Contacting)				None		None		Substantially Equivalent
Shelf Life				5 years		5 years		Substantially Equivalent

Note: *The transceiver is not used for communication with the VERASENSE for Zimmer Biomet Persona or with the VERASENSE for Stryker Triathlon.*

VII. SUMMARY OF DESIGN CONTROLS ACTIVITIES

The risk analysis method used to assess the impact of the modifications to the device was Failure Modes and Effects Analysis (FMEA) described in the FDA-recognized version of ISO 14971. The verification and validation (V&V) activities for the device modifications were executed for compliance with 21 CFR 820.30 design controls and were found acceptable in the predicate submission K180459 and reference submission K150372. The results of V&V support substantial equivalence to the predicate device.

VIII. CONCLUSION

The subject device has the same intended use, indications for use, use environment, functional specifications, wireless communication protocol, operating conditions, storage conditions, sterilization method, packaging, hardware accessory, software accessory and meets the same electrical safety, electromagnetic compatibility, usability standards as the predicate device VERASENSE for Zimmer Biomet Persona. The subject device has the same dimensions, batteries, and patient contacting materials as the reference device.

The differences in the labeling, firmware version, and software application accessory version between the predicate and subject device have been identified. Substantial equivalence has been demonstrated through verification and validation activities. It can be concluded that all technological differences between predicate are safe, effective and do not pose any harm to patients.