August 25, 2020

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

Re: K200587
Trade/Device Name: VERASENSE for Exactech Equinoxe Size 38 mm, VERASENSE for Exactech Equinoxe Size 42 mm, LinkStation MINI, LinkStation MINI Evaluation Kit, VERASENSE Software Application for Shoulder
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ONN
Dated: July 24, 2020
Received: July 27, 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, 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)*

K200587

Device Name

VERASENSE for Exactech Equinoxe

Indications for Use *(Describe)*

The VERASENSE for Exactech Equinoxe is for any medical condition in which reverse Total Shoulder Arthroplasty (rTSA) would be indicated.

For use as a tool for measuring load magnitude and displaying center of load location of the humeral component on the glenosphere component. The device does not make a diagnosis and is not intended to replace a surgeon's clinical judgement.

The VERASENSE for Exactech Equinoxe 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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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: July 24, 2020

II. DEVICE

Name of Device: VERASENSE for Exactech Equinoxe
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 for Exactech Equinoxe device is an intelligent disposable humeral insert trial that measures dynamic loads on the humeral insert and wirelessly transmits the measured load data to the LinkStation MINI and LinkStation MINI Evaluation Kit with VERASENSE Software Application for Shoulder (VSA-S). The VSA-S provides the surgeon with a graphical and numerical presentation of the glenohumeral load magnitude and center of load (COL) location (weighted average) from the humeral to glenoid components. Individual VERASENSE for Exactech Equinoxe devices are packaged sterile, for single patient use with a shim set for thickness adjustments.

V. INDICATIONS FOR USE

The VERASENSE for Exactech Equinoxe is for any medical condition in which Reverse Total Shoulder Arthroplasty (rTSA) would be indicated.

For use as a tool for measuring load magnitude and displaying center of load location of the humeral component on the glenosphere component. The device does not make a diagnosis and is not intended to replace a surgeon's clinical judgement.

The VERASENSE for Exactech Equinoxe 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 accessories intended to support the performance of the parent device are the LinkStation MINI or LinkStation MINI Evaluation Kit
- Patient contacting material used for the bottom housing and adhesive in the vent hole
- Load operating range and accuracy for 5 – 40 lbf

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

- Clinical
  - Intended Use
  - Indications for use
- Technological
  - Labeling
  - Dimensions
  - Load operating range and accuracy for 41 - 70 lbf ≤ 15%
  - Center of Load location accuracy
  - Battery
  - Patient contacting materials (Top housing colorant material, adhesive between top and bottom housing, shims)
  - Shelf life
  - Firmware
  - Software application accessory

	Predicate Device K180459	Subject Device K200587
Sensor and required accessories		
Classification	21 CFR 882.4560	21 CFR 882.4560
Product Code	ONN	ONN
Intended Use	VERASENSE provides a means for orthopedic surgeons to dynamically balance the knee during primary or revision Total Knee Arthroplasty (TKA).	VERASENSE for Exactech Equinoxe provides orthopedic surgeons a tool for a measuring load magnitude and displaying center of load (COL) location (weighted average) of the humeral component on the glenosphere component during a reverse total shoulder arthroplasty (rTSA).
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 for Exactech Equinoxe is indicated for any medical condition in which primary reverse Total Shoulder Arthroplasty (rTSA) would be indicated. For use as a tool for measuring load magnitude and displaying center of load location of the humeral component on the glenosphere component. The device does not make a diagnosis and is not intended to replace a surgeon's clinical judgement. The VERASENSE for Exactech Equinoxe is sterile, for single patient use.
Environment	Hospital	Hospital
Electrical Safety*	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012,	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012,
Electromagnetic Compatibility (EMC)*	IEC 60601-1-2:2014	IEC 60601-1-2:2014
Usability*	62304:2006/A1:2016	62304:2006/A1:2016
Labeling	VERASENSE for Zimmer Biomet Persona product label, VERASENSE knee sensor IFU, and VERASENSE knee sensor and accessories user guide.	VERASENSE for Exactech Equinoxe product label, VERASENSE shoulder sensor IFU, and VERASENSE shoulder sensor and accessories user guide.

*when sensor and accessories tested together

ORTHOSENSOR

			Predicate Device K180459	Subject Device K200587
SENSOR (parent device)				
Mechanical	**Dimensions**		Equal to the dimensions of the implant trial or final liner ± 0.50 mm under all operating conditions	Equal to the dimensions of the implant humeral liner ± 0.50 mm under all operating conditions
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 humeral component of the implant on the sensor (one compartment, three pressure sensors in the compartment)
	Applied Force of Load Sensing	**Load Range and Accuracy**	5-40 lbf ≤ 3.5 lbf	5-40 lbf ≤ 3.5 lbf
			41-70 lbf for reference only	41-70 lbf ≤ 15%
		Maximum Safe Load	70 lbf	70 lbf
	Center of Load (COL) Location		For Reference Only	≤ 3mm
	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.
	Battery		40 min	40 min

ORTHOSENSOR

			Predicate Device K180459	Subject Device K200587
Electrical	Battery	Type	Lithium Ion coin cell	Silver Oxide coin cell
		Operating Voltage and current	3.1 V DC 30mAh	1.55V 27mAh
		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
		Installation and Use	Hand held	Hand held
		Applied Part	Type BF	Type BF
		Protection against harmful ingress of water or particulate matter	IPX4	IPX4
		Mode of Operation	Continuous	Continuous
		Suitability in an oxygen rich environment	No	No
	Wireless Communication	Technology	Radio Frequency	Radio Frequency
		Frequency Band	2402 – 2480 MHz	2402 – 2480 MHz
		Communication Protocol	Bluetooth Low Energy (BLE) 4.2	Bluetooth Low Energy (BLE) 4.2
		Range	2 m	2 m
	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.
	Electrostatic Discharge (ESD)		8kV contact discharge 15 kV air discharge	8kV contact discharge 15 kV air discharge

ORTHOSENSOR

			Predicate Device K180459	Subject Device K200587
Environmental	Operating Conditions	Storage temperature	15 - 37 °C	15 - 37 °C
		Relative humidity	30 - 100% submersion	30 - 100% submersion
	Storage Conditions	Storage temperature	0 - 50 °C	0 - 50 °C
		Relative humidity	10 - 80% non-condensing	10 - 80% non-condensing
		Atmospheric pressure	36 – 106 kPa	36 – 106 kPa
Materials (patient contacting)	Type of Contact		with tissue/bone	with tissue/bone
	Duration of Contact		limited duration contact (<24 hours)	limited duration contact (<24 hours)
	Housing	Top	Colorless Polycarbonate Resin	Colored Polycarbonate Resin (38 mm Blue 550680, 42 mm Yellow 150210)
		Bottom	Colorless Polycarbonate Resin	Colorless Polycarbonate Resin
	Adhesive	Between top and bottom housing	Loctite 3936	Loctite 3311
		For vent hole	Loctite 3936	Loctite 3936
	Shims		10, 11, 12, 13 mm VITREX PolyEtherEtherKetone (PEEK) 381G & stainless-steel metal plates	0, 2.5 mm Colorless Polycarbonate Resin
			14 and 16 mm VITREX PolyEtherEtherKetone (PEEK) 381G	
Sterilization Method			Ethylene Oxide 10^{-6} SAL	Ethylene Oxide 10^{-6} SAL
Shelf Life			14 months	24 months
Packaging			Sterile, Double Tyvek /Film pouches, chipboard box	Sterile, Double Tyvek /Film pouches, chipboard box
Firmware			VERASENSE knee sensor firmware version 2.2.2 which includes communication modes and calibration coefficient.	VERASENSE shoulder sensor firmware version 2.2.6 which includes communication modes and calibration coefficient.

			Predicate Device K180459		Subject Device K200587	
Required Accessories (Intended to support the performance of the VERASENSE sensor parent device)						
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.	
Stand Component			Roll Stand with utility basket and lockable casters	Tablet Kickstand	Roll Stand with utility basket and lockable casters	Tablet Kickstand
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	
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
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 48" (122cm)	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 48" (122cm)
Environmental	Operating Conditions	Storage temperature	-10 - 60 °C		-10 - 60 °C	
		Relative humidity	5 - 95% non-condensing		5 - 95% non-condensing	
	Storage Conditions	Storage temperature	0 - 50 °C		0 - 50 °C	
		Relative humidity	5 - 95% non-condensing		5 - 95% non-condensing	

				Predicate Device K180459		Subject Device K200587	
Transceiver Mount				Mounted on roll stand	Mounted on tripod	Mounted on roll stand	Mounted on tripod
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)	
		IEC 60601-1 Medical Electrical Equipment Classification	Protection Against Electric Shock	Class II		Class II	
			Installation and Use	Portable		Portable	
			Applied Part	No Applied Parts (does not contact patient)		No Applied Parts (does not contact patient)	
			Protection against harmful ingress of water or particulate matter	Not ingress protected		Not ingress protected	
			Mode of Operation	Continuous		Continuous	
			Suitability in an oxygen rich environment	No		No	
		Wireless	**Technology**	Radio Frequency		Radio Frequency	
			Frequency Band	401.05 – 405.55MHz		401.05 – 405.55MHz	
			Communication Protocol	Proprietary		Proprietary	
Sterilization Method				N/A Supplied non-sterile		N/A Supplied non-sterile	
Materials (Patient Contacting)				None		None	
Shelf Life				5 years		5 years	

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

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 Exactech Equinoxe 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 Exactech Equinoxe 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 Exactech Equinoxe, in addition to the biocompatibility testing results of the raw materials, the VERASENSE for Exactech Equinoxe 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 Exactech Equinoxe 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

Verification and validation testing was conducted on the sensor firmware and software application accessory and the documentation provided is as recommended in the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The sensor firmware and software accessory for this device were considered as a "minor" level of concern, since the deice is used as a tool and does not directly drive a decision regarding treatment or therapy.

Performance Testing Bench

The safety performance of the VERASENSE for Exactech Equinoxe 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. CONCLUSION

The subject device has the same general intended use, use environment, operating principle, load accuracy for 5- 40 lbf, maximum safe load, wireless communication protocol, operating conditions, storage conditions, sterilization method, packaging, hardware accessory and meets the same electrical safety, electromagnetic compatibility, usability standards as the predicate device VERASENSE for Zimmer Biomet Persona.

The difference in the indications for use, labeling, dimensions, 41-70 lbf load accuracy, COL location accuracy, battery, patient contacting materials, shelf life, firmware, and software accessory between the predicate and subject have been identified. Substantial equivalence has been demonstrated through verification and validation activities. It can be concluded that all clinical and technological differences between predicate are safe, effective and do not pose any harm to patients.