October 4, 2024

Eventum Orthopaedics Ltd
% Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K241298
Trade/Device Name: QUADSENSE
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: ONN
Dated: May 8, 2024
Received: September 4, 2024

Dear Kelliann Payne:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tejen D. Soni -S

For
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241298

Device Name
QUADSENSE

Indications for Use *(Describe)*
The Quadsense is indicated for use in primary Total Knee Arthroplasty (TKA), where the patella is resurfaced.

For use as a comparative tool to measure patellofemoral joint force.
Quadsense sensor is sterile, for single patient use.

The device does not make a diagnosis and is not intended to replace a surgeon's clinical judgement.

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.

Traditional 510(k) Summary - QUADSENSE

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

1 Submitter

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Date Prepared: October 4, 2024

2 Device

Trade/Proprietary Name:	QUADSENSE
Common or Usual Name:	Intraoperative Orthopaedic Joint Assessment Aid
Regulation Number:	21 CFR 882.4560
Regulation Name:	Stereotaxic Instrument
Regulatory Class:	Class II
Classification Panel:	Neurological Devices
Product Code:	ONN

3 Predicate Device

K180459 VERASENSE for Zimmer Biomet Persona

4 Device Description

The QUADSENSE system has been designed to allow surgeons to compare forces in the patellofemoral joint during total knee surgery.

The QUADSENSE system includes a sensor that attaches to the patella, adjustment shims that attach to the sensor, a control puck, and a touchscreen Panel PC with QUADSENSE software. The patella sensor can take readings of Medial, Lateral, Superior, and Inferior loads during range of motion trials. The sensor records data that is displayed on the Panel PC in real time. The Panel PC remains outside of the sterile field, and the software workflow can be controlled by the surgeon using the control puck, within the sterile field. The Panel PC collects and temporarily stores sensor reading data so the surgeon can view the sensor readings of force through the patellofemoral joint during different stages of the surgical procedure.

The sensor has been designed to attach to the patella at the start of the surgical procedure, following a conservative resection of the patella. This allows the surgeon to take a sensor reading of the patient's force through the patellofemoral joint during range of motion trials, prior to the resurfacing of the femur and the tibia. The surgeon can then take a reading of the force through the patellofemoral joint with the trial femoral and tibial components in situ. This allows the surgeon to assess how the new position of the femoral and tibial components has impacted the patient's force through the patellofemoral joint by comparing the reference reading taken prior to resurfacing to the reading(s) taken following trial implant insertion.

The sensor is supplied with several shims with different thicknesses and angles. By changing the thickness, rotation angulation parameters of the shim attached to the sensor during the surgical procedure the surgeon can assess how change in patella thickness or angulation will impact the force through the patellofemoral joint.

5 Indications for Use

The Quadsense is indicated for use in primary Total Knee Arthroplasty (TKA), where the patella is resurfaced.

For use as a comparative tool to measure patellofemoral joint force. Quadsense sensor is sterile, for single patient use.

The device does not make a diagnosis and is not intended to replace a surgeon's clinical judgement.

6 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 used to measure forces during total knee arthroplasty to ensure the correct positioning of implants.
- Required accessories intended to support the performance of the parent devices are connection to a visual display and software application to provide measurement data (text and graphical) in real time.
- Both QUADSENSE and VERASENSE use attachable shims to modify the geometry of the sensor to assess the effect of different cuts.
- Patient contacting materials have electronic components that are temporarily implanted in the patient for limited duration contact (<24 hours).
- Systems are provided EtO sterilised for single use.

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

- The capacitive sensors are placed in different parts of the knee
- Patient contacting shim material differs, VERASENSE: PolyEtherEtherKetone (PEEK) and stainless steel and QUADSENSE: MAGNUM™ 8391 MED ABS Resin
- Transfer of data to the dedicated computer differs, VERASENSE: Wireless and QUADSENSE: Wired communication.
- Shelf life of QUADSENSE is 12 months.
- IP rating of QUADSENSE is IP55.

Technological differences between the subject device and predicate device have been assessed which has demonstrated that no new questions of safety and effectiveness are raised as a result of these technological differences.

Attribute	[Predicate] VERASENSE for Zimmer Biomet Persona (K180459)	QUADSENSE Subject Device
Classification	21 CFR 882.4560	21 CFR 882.4560
Product Code	ONN	ONN
Intended Use	VERASENSE provides orthopedic surgeons a tool for adjustment of the femoral knee implant during primary or revision Total Knee Arthroplasty (TKA).	QUADSENSE provides orthopedic surgeons a tool for adjustment of the patella implant during primary Total Knee Arthroplasty (TKA).
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.	QUADSENSE is indicated for any medical condition in which primary Total Knee Arthroplasty (TKA) would be indicated, and the patella is resurfaced. For use as a comparative tool to measure patellofemoral joint force. Quadsense sensor is sterile, for single patient use.
Environment	Hospital	Hospital
Electrical Safety	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012.	IEC 60601-1:2005 +AMD1:2012+AMD2:2020
Electromagnetic Compatibility (EMC)	IEC 60601-1-2:2014	IEC 60601-1-2:2014/AMD1:2020
Usability	Usability evaluation performed	Usability evaluation performed according to IEC 62366-1:2015+A1:2020
Labelling	VERASENSE for Zimmer Biomet Persona product label,	Product labelling, IFU, QUADSENSE Surgical

Attribute			[Predicate] VERASENSE for Zimmer Biomet Persona (K180459)	QUADSENSE Subject Device
			VERASENSE knee sensor IFU, and VERASENSE knee sensor and accessories user guide.	Technique User Guide
Sensor				
Mechanical	Dimensions		Equal to the dimensions of the implant trial or final liner ± 0.50 mm under all operating conditions.	Diameter of 40mm. Minimum construct thickness of 6mm but shape and thickness can be adjusted by attachments of shims.
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 record comparative pressure exerted on the patella. Four sensors positioned superiorly, medially, laterally and inferiorly in relation to the anatomy. Sensors record pressure and device acts as a comparator to baseline loads.
	Applied Force of Load Sensing	Load Range and Accuracy	5-40 lbf ≤ 3.5 lbf	Sensor is calibrated at 70 Newtons (15.7 lbf) with 10% error
			41-70 lbf for reference only	
		Maximum Safe Load	70 lbf	16.8kg (37.0 lbf)
	Center of Load (COL) Location		For Reference Only	Measurement is not applicable

Attribute			[Predicate] VERASENSE for Zimmer Biomet Persona (K180459)	QUADSENSE Subject Device
	Communication		Transmission of data from sensor to the LinkStation MINI or LinkStation MINI Evaluation Kit.	Transmission of data from sensor by Analog cable, analog to digital converter, digital cable.
	Battery		40 min, Battery integrated into wireless sensor device.	QUADSENSE has a minimum operational time of 60 minutes on Panel PC battery power under normal use conditions. QUADSENSE sensor does not include a battery and is powered by the Panel PC.
Electrical	Power	Type	Electrically powered via Lithium Ion coin cell	Electrically powered via Panel PC USB 2.0 port, not connected to mains.
		Operating Voltage and current	3.1 V DC 30mAH	5 Vdc, 300 mAdc, 1.5 W MAX
	IEC 60601-1 Medical Electrical Equipment Classification	Protection Against Electric Shock	Internally powered	Electrical insulation
		Installation and Use	Hand held	Portable
		Applied Part	Type BF	Type BF
		Protection against harmful ingress of water of particulate	IPX4	IP55

Attribute			[Predicate] VERASENSE for Zimmer Biomet Persona (K180459)	QUADSENSE Subject Device
		matter		
		Mode of Operation	Continuous	Continuous
		Suitability in an oxygen rich environment	No	No
	Wireless Communication	Purpose	Sensor communicates with Panel PC via wireless connection	Sensor communicates with Panel PC via wired connection. No wireless communication capability is present between the sensor and the Panel PC.
		Technology	Radio Frequency	
		Frequency Band	2402-2480 MHz	
		Communication Protocol	Bluetooth Low Energy (BLE) 4.2	
		Range	2m	
	Electromagnetic Interference (EMI)		Sensor will tolerate typical levels of electromagnetic interface experience in the operating room environment.	QUADSENSE 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
Environmental	Operating Conditions	Operating temperature	15 – 37°C	10 – 35°C
		Relative humidity	30 – 100% submersion	30 – 70%
		Atmospheric	Undisclosed	70 kPa – 106 kPa

Attribute			[Predicate] VERASENSE for Zimmer Biomet Persona (K180459)	QUADSENSE Subject Device
		pressure		
		Maximum Altitude	Undisclosed	2000m above sea level.
	Storage Conditions	Storage temperature	0 – 50°C	10 – 35°C
		Relative humidity	10 – 80% non-condensing	15 – 80% non-condensing
		Atmospheric pressure	36 kPa – 106 kPa	70 kPa – 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	MAGNUM™ 8391 MED ABS Resin
		Bottom	Colorless Polycarbonate Resin	MAGNUM™ 8391 MED ABS Resin
	Attachment mechanism		Attached directly to the trial implants	Attached to the patella using 316L Stainless steel pins
	Shims		VITREX PolyEtherEtherKetone (PEEK) 381G & stainless-steel metal plates	MAGNUM™ 8391 MED ABS Resin
Sterilization Method			Ethylene Oxide 10^{-6} SAL	Ethylene Oxide 10^{-6} SAL
Shelf Life			14 months	12 months
Packaging			Sterile, Double Tyvek / Film pouches, chipboard box	Sterile, Double Paper, PET/PE Film pouches, cardboard box

Attribute	**[Predicate] VERASENSE for Zimmer Biomet Persona (K180459)**	**QUADSENSE Subject Device**
Firmware	VERASENSE knee sensor firmware version 2.2.2 which includes communication modes and calibration coefficient.	QUADSENSE Sensor firmware

7 Performance Data

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

7.1 Biocompatibility Testing

The biocompatibility evaluation for QUADSENSE was conducted in accordance with International Standard ISO 10993-1:2018, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The biocompatibility tests conducted were:

- Cytotoxicity
- Sensitisation
- Irritation
- Acute systemic toxicity
- Material mediated pyrogenicity.

The QUADSENSE 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 QUADSENSE, the device meets the requirements.

7.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on QUADSENSE. The subject device complies with the IEC 60601-1 standard for electrical safety and IEC 60601-1-2 standard for EMC.

7.3 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, "Content of Premarket Submissions for Device Software Functions" The software accessory for this device was determined to require a basic documentation level, since QUADSENSE software application provides data in real time to the surgeon of the amount of force applied through the patellofemoral joint. The QUADSENSE software application does not directly drive a decision regarding treatment or therapy.

7.4 Cybersecurity

Cybersecurity threat modelling was performed. Cybersecurity risk management was performed, and mitigation measures adopted to reduce cybersecurity exposure to an acceptable level. Documentation on cybersecurity measures was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

7.5 Performance Testing

The QUADSENSE has been designed and developed in accordance with Eventum Orthopaedics Standard Operating Procedures for product design and development in line with 21 CFR 820 and in line with an externally certified ISO 13485:2016 quality management system.

The safety performance of the QUADSENSE has been verified and validated to ensure that the product meets its intended use, including:

- Performance Testing (i.e., measurement of load changes due to resurfacing of the patella)
- Biocompatibility Assessment
- Sterilisation
- Packaging Integrity
- Shelf life
- Software Verification and Validation
- Electrical Safety IEC 60601-1
- Electromagnetic Compatibility (EMC) IEC 60601-1-2
- Cybersecurity

7.6 Performance Testing Animal

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

7.7 Performance Testing Clinical

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

8 Conclusions

The subject device QUADSENSE and required accessories have the same intended use, indications for use, environment of use, sterilization method, operating principle, packaging, electrical safety, and electromagnetic compatibility as the predicate device VERASENSE for

Zimmer Biomet Persona and required accessories. The differences in knee location application, wireless communications, materials, IP rating and shelf life have been identified and we determined that they have no impact on safety and effectiveness. Thus, the QUADSENSE is substantially equivalent to the previously cleared K180459 VERASENSE for Zimmer Biomet Persona and required accessories.