September 9, 2025

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

Re: K252524
Trade/Device Name: Quadsense (Quadsense and Quadsense Pro)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ONN
Dated: August 11, 2025
Received: August 11, 2025

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)*
K252524

Device Name
Quadsense (Quadsense and Quadsense Pro)

Indications for Use *(Describe)*
The Quadsense and Quadsense Pro Systems are 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. The Quadsense Sensor and Quadsense Pro Sensor are sterile, for single patient use.

The devices do not make a diagnosis and are 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.

Special 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

Eventum Orthopaedics Ltd
Richmond House
Lawnswood Business Park
Redvers Close
Leeds
LS16 6QY
United Kingdom

Primary Contact / Person: John Naybour, CEO

Date Prepared: August 06, 2025

2 Device

Trade/Proprietary Name:	Quadsense (Quadsense and Quadsense Pro)
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

Trade/Proprietary Name:	QUADSENSE

Common or Usual Name:	Intraoperative Orthopaedic Joint Assessment Aid
510(k) Number	K241298
Manufacturer	Eventum Orthopaedics Ltd
Regulation Number:	21 CFR 882.4560
Regulation Name:	Stereotaxic Instrument
Regulatory Class:	Class II
Classification Panel:	Neurological Devices
Product Code:	ONN

4 Device Description

The Quadsense and Quadsense Pro Systems have been designed to allow surgeons to assess relative quadricep forces at the patellofemoral joint during total knee surgery.

The Quadsense and Quadsense Pro Systems 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 sensors are 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 changes in patella thickness or angulation will impact the force through the patellofemoral joint.

5 Indications for Use

The Quadsense and Quadsense Pro Systems are 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. The Quadsense Sensor and Quadsense Pro Sensor are sterile, for single patient use.

The devices do not make a diagnosis and are not intended to replace a surgeon's clinical judgement.

6 Comparison of Technological Characteristics with the Predicate Device

The Quadsense System remains fundamentally unchanged in its intended use, measurement methods, and core technological principles. Since the clearance of K241298, two categories of modifications have been implemented: (1) minor physical changes introduced under design control and previously assessed via Letter to File (LTF), and (2) software usability enhancements introduced in version 2.1.0, which are the subject of this Special 510(k) submission.

Physical Modifications: Addition of Quadsense Pro and Shelf-Life Extension (Letter to File)

Following the last clearance, the system was updated to include an additional sensor configuration marketed as Quadsense Pro, alongside the original Quadsense. The only physical differences between these configurations are minor geometric changes to the sensor interface and shim design. These modifications were implemented to expand shim configuration options and improve intraoperative usability.

Both Quadsense and Quadsense Pro use identical materials and connection interfaces. The attachment to both bone and sensor remains unchanged.

These changes were assessed in accordance with FDA's guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" and were determined not to impact the intended use or alter the fundamental scientific technology of the system. A comprehensive internal evaluation

confirmed that these modifications did not introduce new or significantly increased risks. The design refinements were fully documented under the company's change control procedures and do not require further review under this Special 510(k); however, they are noted here to provide complete context.

In addition, since the initial 510(k) clearance, the shelf life has been extended from 1 year to 3 years. The shelf-life extension was supported by an accelerated aging study conducted in alignment with the initial 510(k) methods and acceptance criteria. Devices passed all acceptance criteria for functional fit and loading change using the same leg model and firmware calibration as previously validated.

No changes were made to materials, packaging, or sterilization methods. The methods and criteria applied were consistent with those used to support the original shelf-life claim, and results confirmed continued performance through 3 years.

Software Modifications: Usability Enhancements

Software version 2.1.0 introduces usability-focused changes intended to support intraoperative decision-making. The modifications consist of the following enhancements:

- **Quantitative Output for Load Comparison:** The updated software introduces a numerical display that quantifies changes in comparative load readings between the native and resurfaced femoral and tibial components. These outputs are presented as both absolute values and percentage changes, providing supplementary context to the existing graphical feedback (which remains unchanged). These calculations are based on data already acquired by the predicate system and do not involve new measurement methods or hardware inputs.

- **New Software Outputs:**
  Two new warnings have been added to the software:

  - A red text warning if fewer than three distinct load peaks are detected, alerting the user to insufficient data quality.

  - A visual safety alert if the calculated post-resection patella thickness falls below 12 mm, a recognized threshold associated with increased fracture risk.

- **Surgeon-Input Workflow ("Advanced" Workflow):**
  A new, optional workflow enables users to input values such as *Native Patella Thickness*,

Initial Resection Depth, *Implant Brand*, *Implant Thickness*, and *Final Shim Selection*. The software performs simple arithmetic calculations to display:

- **Additional Resection**
- **Patella Thickness After Additional Resection**

These outputs replicate calculations currently performed mentally by surgeons, helping to reduce cognitive burden without introducing new decision logic or automated recommendations.

- **Graphical Display Enhancements:**
  The graphical load display now includes auto-scaling and a calculated percentage change feature, allowing improved visual interpretation of the measured data. A side-by-side comparison of the previous and current graphical outputs is provided.

- **Signal Noise Reduction:**
  A signal filtering feature has been added to reduce high-frequency noise and enhance data clarity. The algorithm applies standard filtering techniques and does not alter the core load signal characteristics.

All new software features are based on surgeon-provided inputs and perform basic arithmetic operations. These changes do not introduce automation of clinical decisions or modify measurement methods. As such, they do not raise new or different questions of safety or effectiveness. The updated outputs serve only to supplement intraoperative interpretation and reduce cognitive effort.

7 Summary of Design Control Activities

The design modifications to the Quadsense system, specifically the enhancements made to the software functionality in both the Streamlined and Advanced workflows, have been subject to a comprehensive risk-based assessment in accordance with the FDA-recognized version of ISO 14971:2019.

Verification and validation activities were conducted in accordance with 21 CFR 820.30 and relevant FDA-recognized consensus standards, including:

- **Software Verification and Validation** in accordance with IEC 62304:2006+A1:2015

- **Cybersecurity testing** performed in accordance with FDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- **Human Factors testing** conducted in accordance with IEC 62366-1:2015/AMD1:2020 and FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices
- **Packaging Validation** leveraged prior validation from the predicate device, as the same packaging materials and processes are used with no changes to the packaging system or device configuration that would impact packaging performance.
- **Post-Aging Functional Testing** was conducted on the Quadsense device following an accelerated aging protocol simulating 3 years of real-time shelf life. All test samples passed predefined acceptance criteria, confirming that device performance was maintained.

The results of the verification and validation activities conducted support substantial equivalence to the predicate device (K241298).

8 Conclusions

The subject device Quadsense has the same intended use, indications for use, environment, sterilization method, operating principle, packaging, electrical safety, and electromagnetic compatibility as the predicate device QUADSENSE.

It can be concluded that the minor technological differences identified are substantially equivalent to the predicate device