September 15, 2022

These Three Medical, LLC
Moj Eram
Regulatory Affairs Correspondent
20860 N. Tatum Blvd., Suite 300
Phoenix, Arizona 85050

Re: K220830
Trade/Device Name: TrueBalance™ Surgical System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: ONN
Dated: August 15, 2022
Received: August 16, 2022

Dear Moj Eram:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220830

Device Name
TrueBalance™ Surgical System

Indications for Use *(Describe)*
TrueBalance™ Surgical System is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated.

For use as a tool to measure implant alignment and for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. TrueBalance™ Surgical System is completely reusable with the exception of the Ultra-Thin Force Sensor which is single 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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510(k) Summary

21 CFR 807.92(a)

1 General Provisions

Submitter Name:	These Three Medical, LLC
Address:	20860 N. Tatum Blvd., Suite 300 Phoenix, AZ 85050
Contact Person:	Jay Pierce
Telephone Number:	480.771.4133
Date of Preparation:	15 August 2022

2 Principle and Regulatory Contacts

Submitted By/Principal Contact:

Contact Name:	Jay Pierce
Title:	President/CEO These Three Medical, LLC
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Phone Number:	480.771.4133
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Regulatory Affairs Correspondance:

Name:	Moj Eram, PhD
Title:	Regulatory Affairs Representative Sage BioPartners, LLC
Phone Number:	801.230.8611 (Mobile)
Email:	moj.eram@sagebiopartners.com

3 Subject Device

Trade Name:	TrueBalance™ Surgical System
Classification Name:	Stereotaxic Instrument
Classification:	Class II
Product Code:	ONN
Regulation Number:	21 CFR 822.4560
Regulation Medical Specialty:	Neurology
Review Panel:	Orthopedic

4 Predicate Devices

1. **VERASENSE For Zimmer Biomet Persona CR C-D/3-9 Left, VERASENSE For Zimmer Biomet Persona CR C-D/3-9 Right, VERASENSE For Zimmer Biomet Persona CR E-F/3-11 Left, VERASENSE For Zimmer Biomet Persona CR E-F/3-11 Right, VERASENSE For Zimmer Biomet Persona CR G-H/7-12 Left (hereafter VERASENSE For Zimmer Biomet Persona)**

Manufacturer:	OrthoSensor, Inc.
510(k) Number:	K193580
Classification:	Class II
FDA Product Code:	ONN (Subsequent OLO)
Regulation Number:	21 CFR 882.4560
Regulation Medical Specialty:	Neurology
Review Panel:	Orthopedic
Device Classification Name:	Intraoperative Orthopedic Joint Assessment Aid

2. **VERASENSE For Zimmer Biomet Persona**

Manufacturer:	OrthoSensor, Inc.
510(k) Number:	K180459
Classification:	Class II
FDA Product Code:	ONN
Regulation Number:	21 CFR 882.4560
Regulation Medical Specialty:	Neurology
Review Panel:	Orthopedic
Device Classification Name:	Intraoperative Orthopedic Joint Assessment Aid

5 Device Description

TrueBalance™ Surgical System provides a means to measure implant alignment and dynamically balance the knee during primary or revision Total Knee Arthroplasty (TKA).

TrueBalance™ Surgical System consists of seven components and one optional component:

1. Electronic Module,
2. Ultra-Thin Force Sensor,
3. Multifunction Alignment Handle,
4. Sensor Covers (8 sizes),
5. Alignment Rod,
6. Sterilization Tray, and
7. TrueBalance™ Software Application (TSA) and Display (iPad)
8. (Optional) Off-the-shelf Tablet Floor Stand for iPad

The TrueBalance™ Surgical System Electronic Module and hardware components are steam sterilizable via autoclave and reusable via a Sterilization Tray. TrueBalance™ Surgical System

Ultra-Thin Force Sensor is single use, packaged non-sterile and is steam sterilizable via autoclave. The TrueBalance™ Surgical System Electronic Module is steam sterilizable via autoclave in either the Sterilization Tray or standard autoclavable pouches.

TrueBalance™ Surgical System measures dynamic loads in the medial and lateral compartments of the knee and static angular measurements for the alignment functionality. The data from the Ultra-Thin Force Sensor and embedded accelerometer is wirelessly transmitted to the TrueBalance™ Software Application (TSA) and Display (iPad) which is located outside the sterile field in the operating room.

6 Indications for Use

TrueBalance™ Surgical System is indicated for any medical condition in which primary or revision Total Knee Arthroplasty (TKA) would be indicated.

For use as a tool to measure implant alignment and for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. TrueBalance™ Surgical System is completely reusable with the exception of the Ultra-Thin Force Sensor which is single use.

7 Comparison of Technological Characteristics with the Predicate Devices

A comparison of the subject device, TrueBalance™ Surgical System and predicate devices, VERASENSE For Zimmer Biomet Persona (K193580) & VERASENSE For Zimmer Biomet Persona (K180459), is based on the following same technologies:

- Electronics and sensors to measure load/force pressure between the femur and tibia in TKA procedures.
- Electronics and accelerometer to measure coronal plane alignment of the tibial resection relative to the patient specific tibia reference axis defined by the system registered landmarks, and numerical value of the varus/valgus tibial mechanical axis.
- Required components to support the system includes a device that communicates via Bluetooth communications and a software application.
- Algorithms to calculate medial and lateral load pressures and present to a user interface.
- Sensor covers (shims) for thickness.

In addition to the similarities stated above, the following technological differences exist between the subject device, TrueBalance™ Surgical System and Predicate devices, VERASENSE For Zimmer Biomet Persona (K193580) & (K180459):

- The Predicate device measures condylar load/force only when the trial hardware components are placed while the TrueBalance™ Surgical System measures condylar loading during gap balancing and trialling phase.
- TrueBalance Surgical System utilizes a Multifunctional Alignment Handle to measure load/force in the medial and lateral compartments, along with load positions in the anterior and posterior compartments.
- In addition to measuring the resected the tibia, TrueBalance Surgical System utilizes an accelerometer and 21inch Alignment Rod to measure coronal plane alignment of the femoral resection relative to the patient specific femur reference axis defined by the

system registered landmarks, and numerical value of the varus/valgus femoral mechanical axis. Note that most conventional instrumentation for TKA procedures includes a spacer block and alignment rod in order to provide the surgeon a tool for visual interpretation of post cut limb alignment, albeit without quantifiable data.

- TrueBalance™ Software Application (TSA) and Display (iPad) presents tibia slope and mechanical axis of the limb.
- The Predicate devices enclose all electronics and sensors in a plastic, hermetically sealed, single use component. The TrueBalance Surgical System electronics module is decoupled from the sensor and the multifunction alignment handle. The system requires assembly in the operating room.
- The Ultra-Thin Force Sensor fits directly between the Multifunction Alignment Handle and numerous size Sensor Covers and is placed between the Femur and resected Tibia with or without trial hardware.
- The entire TrueBalance Surgical System (excluding TSA) is autoclavable.
- TrueBalance Surgical System is reusable. (Exception is the Ultra-thin Force Sensor which single use)
- The TrueBalance™ Surgical System is implant company agnostic system and not dependent on the dimensions of OEM implant components.
- The Predicate devices provide a separate computer (link station) that houses the Software Application. TrueBalance™ Software Application (TSA) and Display (iPad) is provided to the hospital as part of a complete system.

Table 5.1 – Subject and Predicate devices Comparison

	Subject Device TrueBalance™ Surgical System	**Predicate Device VERASENSE for Zimmer Biomet Persona (K193580)**	**Predicate Device VERASENSE for Zimmer Biomet Persona (K180459)**
Sponsor / Owner	These Three Medical, LLC	OrthoSensor, Inc.	OrthoSensor, Inc.
Regulation Number	21 CFR 882.4560	21 CFR 882.4560	21 CFR 882.4560
Product Code	ONN	ONN Subsequent OLO	ONN
Environment for Use	Hospital (operating room)	Hospital (operating room)	Hospital (operating room)
Intended User	Surgeon	Surgeon	Surgeon
General Device Description	A measurement tool to provide the surgeon with quantifiable data relative to load and angular measurements.	A measurement tool to provide the surgeon with quantifiable data relative to load and angular measurements.	A measurement tool to provide the surgeon with quantifiable data relative to load measurements.

Table 5.1 – Subject and Predicate devices Comparison			
	Subject Device TrueBalance™ Surgical System	**Predicate Device VERASENSE for Zimmer Biomet Persona (K193580)**	**Predicate Device VERASENSE for Zimmer Biomet Persona (K180459)**
Principle of Operation	A measurement system used to collect quantifiable data that is useful to the surgeon performing Total Knee Arthroplasty (TKA) procedures. Capacitive sensors on the device measure the pressure exerted by the femoral component of the implant on the sensor. The components include an Electronic Module, Ultra-Thin Force Sensor, Sensor Covers (various thicknesses), Multifunction Alignment Handle, Alignment Rod, and an iPad with a Software Application. The load sensors on the device, measure the pressures exerted between the cut femur and tibia and between the femoral component of the implant on the sensor. The embedded accelerometer works in conjunction with the Alignment Rod and is placed in specified procedural positions, in order to measure angles associated with bone cuts. The Electronic Module is connected via Bluetooth to an iPad hosting the TrueBalance™ Software Application (TSA). The TSA displays both numerically and pictorially load data along with angular measurements (alignment data), according to the description and specifications.	A measurement system used to collect quantifiable data that is useful to the surgeon performing Total Knee Arthroplasty (TKA) procedures. Capacitive sensors on the device measure the pressure exerted by the femoral component of the implant on the sensor. 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. 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.	A measurement system used to collect quantifiable data that is useful to the surgeon performing Total Knee Arthroplasty (TKA) procedures. Capacitive sensors on the device measure the pressure exerted by the femoral component of the implant on the sensor. 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. 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.
Control Mechanism	Microelectronics, sensors and accelerometer to measure the femoral component load and angles of bone cuts.	Microelectronics, capacitive sensors and accelerometer to measure the femoral component load and angles of bone cuts.	Microelectronics, capacitive sensors and accelerometer to measure the femoral component load.

Table 5.1 – Subject and Predicate devices Comparison			
	Subject Device TrueBalance™ Surgical System	**Predicate Device VERASENSE for Zimmer Biomet Persona (K193580)**	**Predicate Device VERASENSE for Zimmer Biomet Persona (K180459)**
Materials			
Electronic Module Top Housing	VICTREX450G Natural PEEK - Material Polyetheretherketone (Electronic Module)	Colored Polycarbonate Resin	Colored Polycarbonate Resin
Electronic Module Bottom Housing	VICTREX450G Natural PEEK - Material Polyetheretherketone (Electronic Module)	Colored Polycarbonate Resin	Colored Polycarbonate Resin
Electronic Module Seal Between Top and Bottom Housing	Silicone Gasket	Loctite	Loctite
Sensor Covers	VICTREX450G Natural PEEK - Material Polyetheretherketone	Shims - Colored Polycarbonate Resin	Shims - Colored Polycarbonate Resin
Sensor	Flex PCB	N/A	N/A
Multifunction Alignment Handle	VICTREX450G Natural PEEK - Material Polyetheretherketone	N/A	N/A
Operation			
Ligament Balancing	TrueBalance™ Surgical System has 2 load transducers per compartment that are used to calculate a composite joint load per compartment. Load transfer is derived from the measured loads. The microelectronics are decoupled from the Ultra-Thin Force Sensor. The Electronic Module is reusable and autoclavable. The Ultra-Thin Force Sensor connects with the electronic module and works in conjunction with the Multifunction Alignment Handle and Sensor Covers (various thickness).	It has 3 load transducers per compartment that are used to calculate a composite joint load per compartment. Load transfer is derived from the measured loads.	It has 3 load transducers per compartment that are used to calculate a composite joint load per compartment. Load transfer is derived from the measured loads.
Alignment Function	Surgical workflow – The surgeon follows standard instrumented surgical technique and makes the distal femur and proximal tibia cuts. The system is inserted into the gap that has been created.	The varus/valgus angle of the resected tibia in the coronal plane is calculated using the established tibia reference frame and the patient tibial length measured by the surgeon and entered into the	N/A

Table 5.1 – Subject and Predicate devices Comparison			
	Subject Device TrueBalance™ Surgical System	**Predicate Device VERASENSE for Zimmer Biomet Persona (K193580)**	**Predicate Device VERASENSE for Zimmer Biomet Persona (K180459)**
	The alignment measurement tool is used to assist the surgeon in confirming the cut varus/valgus angles of the tibia and femur, posterior slope of tibia and mechanical axis of limb. Registration of anatomy includes capturing the center of the femoral head and center of the ankle. The mechanical alignment is calculated and defined as the axis from the center of the femoral head to the intercondylar notch and extends further down from the center of the proximal tibia to the center of the ankle. Posterior slope is in the sagittal plane of the tibia. Differences: The TrueBalance™ Surgical System uses a static measurement system w/accelerometer versus IMU, a unique algorithm, along with the utilization of a standard TKA alignment rod to facilitate data collection. This is a real-time measurement system versus a navigation system that directs bone cuts.	software application. The tibial mechanical alignment range is varus/valgus ±7° with an accuracy of ±3°. The VERASENSE for Zimmer Biomet Persona includes an accelerometer and gyroscope that make up the inertial measurement unit (IMU). The IMU is calibrated to removed fixed biases, scale errors, and misalignment errors in both the accelerometer, and gyroscope. The accelerometer provides the linear acceleration, while gyroscope provides the angular velocity, which are used to determine the frame of reference for the IMU. The VERASENSE for Zimmer Biomet Persona registers the first anatomical landmark, the center of the tibia, based on the placement of the VERASENSE for Zimmer Biomet device in the tibial tray implant. The IMU within the VERASENSE for Zimmer Biomet Persona is centered with respect to the implant tibial tray, with a specific offset value for each size and side of the device. The second anatomical landmark, the lateral center of the heel's calcaneus, is registered when the surgeon takes the leg through a pivot motion with the heel stabilized, while the hip and the pelvis are stable through the patient position.	

Table 5.1 – Subject and Predicate devices Comparison			
	Subject Device TrueBalance™ Surgical System	**Predicate Device VERASENSE for Zimmer Biomet Persona (K193580)**	**Predicate Device VERASENSE for Zimmer Biomet Persona (K180459)**
Communication & Display	**TrueBalance™ Electronics Module:** Bluetooth 4.2 **Software Application (TSA) and Display:** 9th Generation Apple iPad with 10.2" Display, Bluetooth 4.2 Compatible, WIFI	**Sensor:** Bluetooth 4.2 compatible **LinkStation MINI/LinkStation MINI Evaluation Kit**: Bluetooth 4.2 compatible, WIFI	**Sensor:** Bluetooth 4.2 compatible **LinkStation MINI/LinkStation MINI Evaluation Kit**: Bluetooth 4.2 compatible, WIFI
Electrical Details (power, outlets, voltage, etc.)	**TrueBalance™ Electronic Module:** Internally powered high temp lithium battery (3.6V 2/3AA) **iPad:** AC power **Protection against electrical Shock:** Type BF Applied **Electromagnetic Interference (EMI):** will tolerate typical levels of electromagnetic interface **Electrostatic Discharge (EDS)** will tolerate exposure to 8kV contact discharge and 8 kV air discharge. The TrueBalance™ Software Application (TSA) and Display (iPad) runs on a 9th generation iPad.	**Sensor:** Internally powered (3.1V DC) **LinkStation MINI /LinkStation MINI Evaluation Kit:** AC Power **Protection against electrical Shock:** Type BF Applied **Electromagnetic Interference (EMI):** will tolerate typical levels of electromagnetic interface **Electrostatic Discharge (EDS)** will tolerate exposure to 8kV contact discharge and 8 kV air discharge. **Display Unit Protection Against Electrical Shock** Class I (65W universal 3-pin jack, 100-240V, 1.5A, 50-60Hz) **Transceiver Unit Protection Against Electrical Shock** Class II USB powered and intended to be connected to the USB port of the LinkStation MINI display unit (5 V dc)	**Sensor:** Internally powered (3.1V DC) **LinkStation MINI /LinkStation MINI Evaluation Kit:** AC Power **Protection against electrical Shock:** Type BF Applied **Electromagnetic Interference (EMI):** will tolerate typical levels of electromagnetic interface **Electrostatic Discharge (EDS)** will tolerate exposure to 8kV contact discharge and 8 kV air discharge. **Display Unit Protection Against Electrical Shock** Class I (65W universal 3-pin jack, 100-240V, 1.5A, 50-60Hz) **Transceiver Unit Protection Against Electrical Shock** Class II USB powered and intended to be connected to the USB port of the LinkStation MINI display unit (5 V dc)

Table 5.1 – Subject and Predicate devices Comparison				
	Subject Device TrueBalance™ Surgical System		**Predicate Device VERASENSE for Zimmer Biomet Persona (K193580)**	**Predicate Device VERASENSE for Zimmer Biomet Persona (K180459)**
Range (Meter)	2m		2m	2m
Performance Specifications (Load Balancing)	**Operating Range**	0 - 160 LBF	N/A	5 - 40 LBF
	Load Accuracy	±3.0 LB For ± 7.5% (whichever is greater)	N/A	±3.5 LBF
	Load Values Displayed for Reference only	>160 LBF	N/A	41-70 LBF
	Maximum Safe Load	160 LBF (per condyle)	N/A	70 LBF
	A-P Condylar Position & M-L Distribution Accuracies	Equal to or better than ± 25%	N/A	COL for Reference Only
Performance Specifications (Alignment)	**Tibia Varus/Valgus**	± 0.9° 95% Confidence	Range is varus/valgus ± 7° with an accuracy of ± 3°	N/A
	Femur Varus/Valgus	± 1.2° 95% Confidence	N/A	N/A
	Posterior Slope	± 1.0° 95% Confidence	N/A	N/A
	Mechanical Axis	± 1.5° 95% Confidence	N/A	N/A
Software	The TrueBalance™ Software Application (TSA) and Display (iPad) calculates force vectors and positional data, displayed both numerically and pictorially load data versus position, according to the description and specifications. For alignment, the TSA displays the		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. For alignment,	The VERASENSE Software Application calculates force vectors and positional data, display both numerically and pictorially load data versus position, according to the

Table 5.1 – Subject and Predicate devices Comparison			
	Subject Device TrueBalance™ Surgical System	**Predicate Device VERASENSE for Zimmer Biomet Persona (K193580)**	**Predicate Device VERASENSE for Zimmer Biomet Persona (K180459)**
	tibial varus/valgus for the tibia, femur, slope and mechanical alignment. **User Interface:** Component with iPad with a graphical user interface **iPad Resolution:** 10.2" screen, 2160 x 1620 resolution at 264 ppi **Operating System Compatibility (display Unit):** iOS – iPad Version 15.6 or later	the VSA displays the tibial varus/valgus alignment angle numerically using tibial length, positional data, angular velocity. **User Interface:** Accessory with tablet computer with a graphical user interface **Operating System Compatibility (display Unit):** Microsoft Windows 10	description and specifications. Alignment N/A **User Interface:** Accessory with tablet computer with a graphical user interface **Operating System Compatibility (display Unit):** Microsoft Windows 10
Software LOC	**Minor**	**Minor**	**Minor**
Sterilization Method	**Electronics Module:** Steam Sterilization via Autoclave **Ultra-Thin Force Sensor:** Steam Sterilization via Autoclave O**ther components:** Steam Sterilization via Autoclave	**Sensor:** Ethylene Oxide 10-6 SAL **LinkStation MINI/LinkStation MINI Evaluation Kit:** Non-Sterile	**Sensor:** Ethylene Oxide 10-6 SAL **LinkStation MINI/LinkStation MINI Evaluation Kit:** Non-Sterile
Shelf Life	Ultra-Thin Force Sensor: 17 months PEEK Components: 24 months prior to first reprocessing cycle	3 Months	3 Months
Packaging	TrueBalance™ Surgical System is not offered sterile. <u>Ultra-Thin Force Sensor:</u> 50 sensors are bagged and labelled (single Use) <u>Electronic Module:</u> 5 per box and labeled <u>Kitted Sterilization Tray</u>: include, Multifunction Alignment Handle, Sensor Covers (8 sizes), Alignment Rod, boxed and labeled	**Sensor:** double pouched, sterile **Accessories:** LinkStation MINI - Wood box LinkStation MINI Evaluation Kit – Waterproof plastic case	**Sensor:** double pouched, sterile **Accessories:** LinkStation MINI - Wood box LinkStation MINI Evaluation Kit – Waterproof plastic case

Table 5.1 – Subject and Predicate devices Comparison			
	Subject Device TrueBalance™ Surgical System	**Predicate Device VERASENSE for Zimmer Biomet Persona (K193580)**	**Predicate Device VERASENSE for Zimmer Biomet Persona (K180459)**
	All components are steam sterilizable via autoclave with the exception of the iPad.		
Ingress of Liquids	Electronic Module: IPX7 Display Unit: N/A, the iPad does not come in contact with fluids (outside of the sterile field).	**Sensor:** Rated IPX4 **Display Unit:** Rated IP54	**Sensor:** Rated IPX4 **Display Unit:** Rated IP54
Electrical Safety	AAMI ANSI ES60601-1:2005/A1:2012	AAMI ANSI ES60601-1:2005	AAMI ANSI ES60601-1:2005
Electromagnetic Capability (EMC)	IEC 60601-1-2:2014	IEC 60601-1-2:2007/AC:2010	IEC 60601-1-2:2007/AC:2010
Sensor Compatibility	Implant Company Agnostic	Zimmer Biomet: Persona	Zimmer Biomet: Persona
Single Use / Reusable	TrueBalance™ Surgical System is reusable with the exception of the Ultra-Thin Force Sensor component which is single use only.	Single Use	Single Use
Anatomical Site Use	TKA Procedures	TKA Procedures	TKA Procedures
Patient Contacting	Yes – Sensor Covers, Multifunction Alignment Handle, and Ultra-Thin Force Sensor are direct patient contacting components. Evaluated according to ISO 10993-1:2018	None	None
Prescription or Over-the-Counter	Prescription Only	Prescription Only	Prescription Only

8 Safety and Performance Tests

To establish substantial equivalence and a shelf-life period for the subject device, TrueBalance™ Surgical System, the tests performed in Table 5.2 were completed with results demonstrating that acceptance criteria were met and that the subject device is substantially equivalent in performance as compared to the cited predicate devices, VERASENSE For Zimmer Biomet Persona (K193580) and VERASENSE For Zimmer Biomet Persona (K180459).

Risk management, including a failure mode and effects analysis (FMEA), of the subject device was conducted in accordance with ISO 14971:2019, *Medical Devices – Application of risk management to medical devices*.

Table 5.2 – The Subject Device, TrueBalance™ Surgical System, Safety and Performance Testing Summary

Test	Standards	Test Description	Result
Software Lifecycle	IEC 62304	Software Development and V&V	Pass
Electrical Safety	IEC 60601-1	Safety Testing	Pass
Electromagnetic Compatibility	IEC 60601-1-2	EMC Testing	Pass
EMC Testing	EN 301 489-1 v2.2.3 EN 301 489-17 v3.2.2	EMC Testing	Pass
Radio Frequency	47 CFR Part 15.247	FCC Testing	Pass
Reprocessing	AAMI TIR 30 AAMI TIR 12 ISO 17664	Manual cleaning and automated wash	Pass
Sterilization	ISO 17665-1 ISO 17665-2 ISO 17664 ISO 11737-2 ISO 11138-7	Autoclave steam sterilization	Pass
Biocompatibility	ISO 10993-1 and Family	• Cytotoxicity • Irritation • Sensitization • Acute systemic toxicity • Material mediated pyrogenicity	Pass
Shelf Life	Real Time	Tox, FT-IR and TOC	Pass
Packaging	ASTM D4169-16	Drop, Vibration, Environmental Condition	Pass
Stability Studies	ISO 10993-5	Cytotoxicity, FT-IR & TOC	Pass
Usability Engineering / Cadaver Labs	IEC 62366-1 & IEC 60601-1-6 Internal Protocol	Usability Testing Cadaver Labs	Pass
Load / Force Performance Testing	Internal Protocol	Load/Force Testing	Pass
Alignment Performance Testing	Internal Protocol	Alignment Testing	Pass
Water Ingress Rating	IEC 60529	IPX7 Water Ingress Test (electronic Module Only)	Pass

Table 5.2 – The Subject Device, TrueBalance™ Surgical System, Safety and Performance Testing Summary			
Test	**Standards**	**Test Description**	**Result**
Shelf Life	ASTM F1980	Accelerated Aging studies	Pass
Performance Testing – Animal	N/A	Animal performance testing was not required to demonstrate substantial equivalence	N/A
Performance Testing – Clinical	N/A	Clinical performance testing was not required to demonstrate substantial equivalence	N/A

9 Summary of Substantial Equivalence

TrueBalance™ Surgical System has the same intended use as the predicate devices, VERASENSE For Zimmer Biomet Persona (K193580) and VERASENSE For Zimmer Biomet Persona (K180459), as well as substantially equivalent technological characteristics and is as safe and effective as the predicate device. The differences in the technological characteristics do not raise different questions of safety or efficacy. The subject device, TrueBalance™ Surgical System, is substantially equivalent to its predicate devices.

Based on the intended use, technological characteristics, and safety and performance testing, the subject device, TrueBalance™ Surgical System, met the requirements that are considered sufficient for its intended use and are as safe and as effective as the predicate devices, VERASENSE For Zimmer Biomet Persona (K193580) and VERASENSE For Zimmer Biomet Persona (K180459).