March 14, 2024

Stryker Leibinger GmbH & Co. KG
Megan Guilbault
Staff Regulatory Affairs Specialist
Bötzinger Straße 41
Freiburg Baden-Wurttemberg, D-79111
Germany

Re: K233542
Trade/Device Name: Ortho Guidance Precision Knee Software; Ortho Guidance Express Knee Software; Ortho Guidance Versatile Hip Software; Q Guidance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 15, 2023
Received: December 15, 2023

Dear Megan Guilbault:

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.

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,

Shumaya Ali -S

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.

Submission Number *(if known)*

K233542

Device Name

Ortho Guidance Precision Knee Software;
Ortho Guidance Express Knee Software;
Ortho Guidance Versatile Hip Software;
Q Guidance System

Indications for Use *(Describe)*

Ortho Guidance Precision Knee Software:
The Stryker guidance systems, with the Ortho Guidance Precision Knee Software, are intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. The systems can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The systems are indicated for conditions of the knee joint in which the use of computer-assisted surgery may be appropriate.

Ortho Guidance Express Knee Software:
The Stryker guidance systems, with the Ortho Guidance Express Knee Software, are intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. The systems can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The systems are indicated for conditions of the knee joint in which the use of computer-assisted surgery may be appropriate.

Ortho Guidance Versatile Hip Software:
The Stryker guidance systems, with the Ortho Guidance Versatile Hip Software, are intended as a planning and intraoperative guidance system to enable open computer-assisted surgery.
The systems can be used for intraoperative guidance where a reference to a rigid anatomical structure such as but not limited to the pelvis, or femur, can be identified.
The systems are indicated for conditions of the hip joint in which the use of computer-assisted surgery may be appropriate.
The system is indicated for the following surgical procedures:
- Total Hip Arthroplasty (THA)
- Precisely positioning instruments, implants, and bony tissue during orthopaedic hip surgery
- Revisions

Q Guidance System:
The Q Guidance System is intended as an aid for precisely locating anatomical structures in open or percutaneous computer assisted surgery. When used with the Ortho Guidance Precision Knee, Express Knee, or Versatile Hip Software, the Q Guidance System is indicated for any medical condition in which the use of computer assisted planning and surgery may be appropriate and where reference to a rigid anatomical structure such as the femur, tibia, or long bone can be identified.

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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Submitter Information

1.0 This Premarket Notification is submitted by:

Stryker Leibinger GmbH & Co. KG
Bötzinger Straße 41
79111 Freiburg, Germany

2.0 Contact Information

Contact name: Megan Guilbault
Cellular Telephone: (401) 241-6152
Email: megan.guilbault@stryker.com
Date Prepared: March 14, 2024

3.0 Device Name

Table 1: Device Name

Subject (Modified) Device Information	
Trade/ Proprietary Name	Ortho Guidance Precision Knee Software Ortho Guidance Express Knee Software Ortho Guidance Versatile Hip Software Stryker Q Guidance System
Common Name	Stereotaxic Instruments
Classification	Class II
Classification Product Code	OLO
Classification Name	Orthopedic Stereotaxic Instrument
Classification Regulation	21 CFR 882.4560
Review Panel	Orthopedic

5.0 Predicate Devices

The following are the legally marketed predicate devices for the subject devices included in this Traditional 510(k). The primary predicate device is K223767.

Table 2: Predicate Device List

Subject Device	Predicate Device Trade Name	510(k)	Product Code	Manufacturer
Ortho Guidance Precision Knee Software	Ortho Guidance Precision Knee Software	K223767	OLO	Stryker Leibinger GmbH & Co. KG
Ortho Guidance Express Knee Software	Ortho Guidance Express Knee Software	K223767	OLO	Stryker Leibinger GmbH & Co. KG
Ortho Guidance Versatile Hip Software	Ortho Guidance Versatile Hip Software	K223767	OLO	Stryker Leibinger GmbH & Co. KG
Q Guidance System	Q Guidance System	K212194	HAW	Stryker Leibinger GmbH & Co. KG

6.0 Device Description

The purpose of this Traditional 510(k) submission is to seek clearance for the addition of a Stryker guidance system to the indications of 3 Ortho Guidance software applications. The subject devices in scope of this submission are outlined in Table 1 with the predicate information in Table 2. The devices in scope of this submission, Ortho Guidance Precision Knee Software, Ortho Guidance Express Knee Software, Ortho Guidance Versatile Hip Software, and the Q Guidance System work within an ecosystem with a host of other existing smart devices and accessories that will be demonstrated to be compatible with the subject devices but are not in scope of this submission.

The system is intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. It allows for the localization of surgical instruments, and visualization of their position relative to patient specific anatomical landmark information, assisting the surgeon in performing the intervention at a high level of precision. The system uses active optical tracking technology to display to the surgeon the intraoperative location of navigated surgical instruments relative to a computed anatomical model. The computed model is based on an intraoperative anatomy survey of the pelvis and/or leg.

6.6 Indications for Use

6.6.1 Ortho Guidance Precision Knee Software

The Stryker guidance systems, with the Ortho Guidance Precision Knee Software, are intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. The systems can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The systems are indicated for conditions of the knee joint in which the use of computer-assisted surgery may be appropriate.

6.6.2 Ortho Guidance Express Knee Software

The Stryker guidance systems, with the Ortho Guidance Express Knee Software, are intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. The systems can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The systems are indicated for conditions of the knee joint in which the use of computer-assisted surgery may be appropriate.

6.6.3 Ortho Guidance Versatile Hip Software

The Stryker guidance systems, with the Ortho Guidance Versatile Hip Software, are intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. The systems can be used for intraoperative guidance where a reference to a rigid anatomical structure such as but not limited to the pelvis, or femur, can be identified. The systems are indicated for conditions of the hip joint in which the use of computer-assisted surgery may be appropriate.

The system is indicated for the following surgical procedures:

- Total Hip Arthroplasty (THA)
- Precisely positioning instruments, implants, and bony tissue during orthopaedic hip surgery
- Revisions

6.6.4 Stryker Q Guidance System

The Q Guidance System is intended as an aid for precisely locating anatomical structures in open or percutaneous computer assisted surgery. When used with the Ortho Guidance Precision Knee, Express Knee, or Versatile Hip Software, the Q Guidance System is indicated for any medical condition in which the use of computer assisted planning and surgery may be appropriate and where reference to a rigid anatomical structure such as the femur, tibia, or long bone can be identified.

6.7 Comparison of Technological Characteristics

A comparison of the technological characteristics of the subject devices included in the scope of this Traditional 510(k) is included in the tables below.

6.7.1 Technological Comparison between the Ortho Guidance Precision Knee Software and its predicate

The technological comparison between the subject device (Ortho Guidance Precision Knee Software) and the predicate device (Ortho Guidance Precision Knee Software) is included in Table 3 below. The predicate received clearance per 510(k) number K223767.

Table 3: Technological Comparison between the Ortho Guidance Precision Knee Software and its Predicate

Item	**Subject Device:** Ortho Guidance Precision Knee Software	**Predicate Device:** Ortho Guidance Precision Knee Software (K223767)	**Changes**
Platform Compatibility	• Stryker Ortho Q Guidance System • Stryker Q Guidance System	• Stryker Ortho Q Guidance System	Added Stryker Q Guidance System
Compatible Operating System	• Linux (Yocto Distro Version 3.1, codename “dunfell”).	• Linux (Yocto Distro Version 3.1, codename “dunfell”).	No change
Workflow Steps	• Patient Preparation • System Set-up • Patient Registration • Analyze Initial Alignment • Size and Position Implant • Resect Bones • Analyze Trial Implant • Analyze Final Implant	• Patient Preparation • System Set-up • Patient Registration • Analyze Initial Alignment • Size and Position Implant • Resect Bones • Analyze Trial Implant • Analyze Final Implant	No change
Localization and Tracking Technology	Infrared Optical Active Tracking: Infrared light emitted by diodes placed in specific locations on tracked instruments is sensed by the navigation camera on the platform, which allows for computation of the position and orientation of the tracked instruments.	Infrared Optical Active Tracking: Infrared light emitted by diodes placed in specific locations on tracked instruments is sensed by the navigation camera on the platform, which allows for computation of the position and orientation of the tracked instruments.	No change

Operating Principle	• The software is installed on the computer that is part of the platform • The software displays the planned items with navigational information on a monitor	• The software is installed on the computer that is part of the platform • The software displays the planned items with navigational information on a monitor	No change
Control Mechanism	• From outside the sterile surgical field, the software can be controlled using the mouse, or touchscreen. • From the sterile field, the software can be controlled using the active optical instruments. • The information of the software is displayed on a monitor. • On the monitor, the blue highlighted button indicates the selected function.	• From outside the sterile surgical field, the software can be controlled using the mouse, or touchscreen. • From the sterile field, the software can be controlled using the active optical instruments. • The information of the software is displayed on a monitor. • On the monitor, the blue highlighted button indicates the selected function.	No change
Intended Use Environment	Operating Room (OR)	Operating Room (OR)	No change
Intended Users	Trained clinical staff	Trained clinical staff.	No change
Graphical User Interface (GUI)	• Black style graphical user interface. • Main Menu shows the workflow steps that are available throughout the surgical procedures. Each screen of each workflow step accommodates a task instruction below the graphics.	• Black style graphical user interface. • Main Menu shows the workflow steps that are available throughout the surgical procedures. Each screen of each workflow step accommodates a task instruction below the graphics.	No change
User Interface	• Surgeon's Monitor • Small Touch Monitor • Mouse • Buttons on active optical instruments	• Surgeon's Monitor • Small Touch Monitor • Mouse • Buttons on active optical instruments	No change

6.7.2 Technological Comparison between the Ortho Guidance Express Knee Software and its predicate

The technological comparison between the subject device (Ortho Guidance Express Knee Software) and the predicate device (Ortho Guidance Express Knee Software) is included in Table 4 below. The predicate received clearance per 510(k) number K223767.

Table 4: Technological Comparison between the Ortho Guidance Express Knee Software and its Predicate

Item	Subject Device: Ortho Guidance Express Knee Software	Predicate Device: Ortho Guidance Express Knee Software (K223767)	Changes
Platform Compatibility	• Stryker Ortho Q Guidance System • Stryker Q Guidance System	• Stryker Ortho Q Guidance System	Added Stryker Q Guidance System
Compatible Operating System	• Linux (Yocto Distro Version 3.1, codename "dunfell").	• Linux (Yocto Distro Version 3.1, codename "dunfell").	No change
Workflow Steps	• Patient Preparation • System Set-up • Patient Registration • Analyze Initial Alignment • Size and Position Implant • Resect Bones • Analyze Trial Implant • Analyze Final Implant	• Patient Preparation • System Set-up • Patient Registration • Analyze Initial Alignment • Size and Position Implant • Resect Bones • Analyze Trial Implant • Analyze Final Implant	No change
Localization and Tracking Technology	Infrared Optical Active Tracking: Infrared light emitted by diodes placed in specific locations on tracked instruments is sensed by the navigation camera on the platform, which allows for computation of the position and orientation of the tracked instruments.	Infrared Optical Active Tracking: Infrared light emitted by diodes placed in specific locations on tracked instruments is sensed by the navigation camera on the platform, which allows for computation of the position and orientation of the tracked instruments.	No change
Operating Principle	• The software is installed on the computer that is part of the platform • The software displays the planned items with navigational information on a monitor	• The software is installed on the computer that is part of the platform • The software displays the planned items with navigational information on a monitor	No change
Control Mechanism	• From outside the sterile surgical field, the software can be controlled using the mouse, or touchscreen. • From the sterile field, the software can be controlled using the active optical instruments. • The information of the software is displayed on a monitor. • On the monitor, the blue highlighted button indicates the selected function.	• From outside the sterile surgical field, the software can be controlled using the mouse, or touchscreen. • From the sterile field, the software can be controlled using the active optical instruments. • The information of the software is displayed on a monitor. • On the monitor, the blue highlighted button indicates the selected function.	No change
Intended Use Environment	Operating Room (OR)	Operating Room (OR)	No change
Intended Users	Trained clinical staff	Trained clinical staff	No change
Graphical User Interface (GUI)	• Black style graphical user interface. • Main Menu shows the workflow steps that are available throughout the surgical procedures. Each screen of each workflow step accommodates a task instruction below the graphics.	• Black style graphical user interface. • Main Menu shows the workflow steps that are available throughout the surgical procedures. Each screen of each workflow step accommodates a task instruction below the graphics.	No change
User Interface	• Surgeon's Monitor • Small Touch Monitor • Mouse	• Surgeon's Monitor • Small Touch Monitor • Mouse • Buttons on active optical instruments	No change

	• Buttons on active optical instruments		
Tracking Signal Output	Visual and auditory	Visual and auditory	No change

6.7.3 Technological Comparison between the Ortho Guidance Versatile Hip Software and its predicate

The technological comparison between the subject device (Ortho Guidance Versatile Hip Software) and the predicate device (Ortho Guidance Versatile Hip Software) is included in Table 5 below. The predicate received clearance per 510(k) number K223767.

Table 5: Technological Comparison between the Ortho Guidance Versatile Hip Software and its Predicate

Item	**Subject Device:** Ortho Guidance Versatile Hip Software	**Predicate Device:** Ortho Guidance Versatile Hip Software (K223767)	**Changes**
Platform Compatibility	• Stryker Ortho Q Guidance System • Stryker Q Guidance System	• Stryker Ortho Q Guidance System	Added Stryker Q Guidance System
Operating System	• Linux (Yocto Distro Version 3.1, codename "dunfell").	• Linux (Yocto Distro Version 3.1, codename "dunfell").	No change
Workflow Steps	• Patient Preparation • System Set-up • Patient Registration • Analyze Initial Alignment • Size and Position Implant • Resect Bones • Analyze Trial Implant • Analyze Final Implant	• Patient Preparation • System Set-up • Patient Registration • Analyze Initial Alignment • Size and Position Implant • Resect Bones • Analyze Trial Implant • Analyze Final Implant	No change
Localization and Tracking Technology	Infrared Optical Active Tracking: Infrared light emitted by diodes placed in specific locations on tracked instruments is sensed by the navigation camera on the platform, which allows for computation of the position and orientation of the tracked instruments.	Infrared Optical Active Tracking: Infrared light emitted by diodes placed in specific locations on tracked instruments is sensed by the navigation camera on the platform, which allows for computation of the position and orientation of the tracked instruments.	No change
Operating Principle	• The software is installed on the computer that is part of the platform • The software displays the planned items with navigational information on a monitor	• The software is installed on the computer that is part of the platform • The software displays the planned items with navigational information on a monitor	No change
Control Mechanism	• From outside the sterile surgical field, the software can be controlled using the mouse, or touchscreen. • From the sterile field, the software can be controlled using the active optical instruments. • The information of the software is displayed on a monitor. • On the monitor, the blue highlighted button indicates the selected function.	• From outside the sterile surgical field, the software can be controlled using the mouse, or touchscreen. • From the sterile field, the software can be controlled using the active optical instruments. • The information of the software is displayed on a monitor. • On the monitor, the blue highlighted button indicates the selected function.	No change

Intended Use Environment	Operating Room (OR)	Operating Room (OR)	No change
Intended Users	Trained clinical staff	Trained clinical staff.	No change
Graphical User Interface (GUI)	• Black style graphical user interface. • Main Menu shows the workflow steps that are available throughout the surgical procedures. Each screen of each workflow step accommodates a task instruction below the graphics.	• Black style graphical user interface. • Main Menu shows the workflow steps that are available throughout the surgical procedures. Each screen of each workflow step accommodates a task instruction below the graphics.	No change
User Interface	• Surgeon's Monitor • Small Touch Monitor • Mouse • Buttons on active optical instruments	• Surgeon's Monitor • Small Touch Monitor • Mouse • Buttons on active optical instruments	No change
Tracking Signal Output	Visual and auditory	Visual and auditory	No change

6.7.4 Technological Comparison between the Stryker Q Guidance System and its predicate

The technological comparison between the subject device (Styker Q Guidance System) and the predicate device (Stryker Q Guidance System) is included in Table 6 below. The predicate received clearance per 510(k) number K212194.

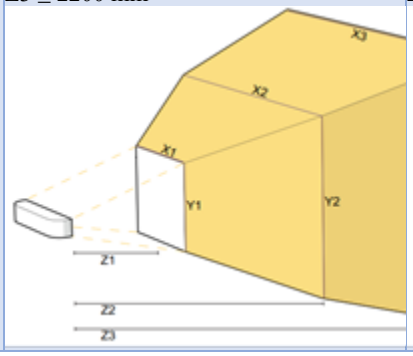
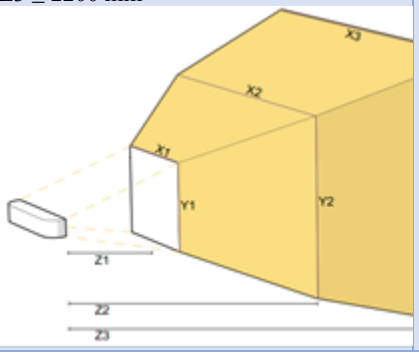
Table 6-6: Technological Comparison between the Stryker Q Guidance System and Stryker Q Guidance System

Item	**Subject Device:** Stryker Q Guidance System	**Predicate Device:** Stryker Q Guidance System (K212194)	**Changes**
Operating Principle	• The software is installed on the computer that is part of the platform • Images are imported in DICOM format • The software displays images and planned items with navigational information on a monitor	• The software is installed on the computer that is part of the platform • Images are imported in DICOM format • The software displays images and planned items with navigational information on a monitor	Identical – the Ortho Guidance Software applications are imageless and do use the image import functionality that is available on the Q Guidance System.
Dimensions	Outer dimensions: • Length x Width x Height: 950 x 720 x 1950 mm • Weight: 265 kg	Outer dimensions: • Length x Width x Height: 950 x 720 x 1950 mm • Weight: 265 kg	No change
Environmental Conditions	Operation: • Temperature: 10°C – 30°C • Relative humidity: 30% – 75% • Atmospheric pressure: 70 kPa – 106 kPa Transportation: • Temperature: -10°C – 50°C • Relative humidity: 10% – 90% • Atmospheric pressure: 70 kPa – 106 kPa Storage: • Temperature: 10°C – 50°C • Relative humidity: 10% – 85%	Operation: • Temperature: 10°C – 30°C • Relative humidity: 30% – 75% • Atmospheric pressure: 70 kPa – 106 kPa Transportation: • Temperature: -10°C – 50°C • Relative humidity: 10% – 90% • Atmospheric pressure: 70 kPa – 106 kPa Storage: • Temperature: 10°C – 50°C • Relative humidity: 10% – 85%	No change

	• Atmospheric pressure: 70 kPa – 106 kPa	• Atmospheric pressure: 70 kPa – 106 kPa	
WiFi Connectivity	TP-Link Archer T9UH, WiFi-USB - Adapter/Dongle	TP-Link Archer T9UH, WiFi-USB - Adapter/Dongle	No change
Cable Guard Cart Castors	Spatula front mounted design	Spatula front mounted design	No change
Keyboard and Mouse	• Man & Machine Petite Mouse Medical grade mini mouse; silicon covered; can be disinfected ActiveKey, Medical grade keyboard; silicone covered; can be disinfected	• Man & Machine Petite Mouse Medical grade mini mouse; silicon covered; can be disinfected • ActiveKey, Medical grade keyboard; silicone covered; can be disinfected	No change
Application PC	Mainboard: MB-815-00A1E; Advantech Standard Server Board	Mainboard: MB-815-00A1E; Advantech Standard Server Board	No change
	• Intel Xeon 4109T Silver • 8 Cores, 16 Threads • Base Clock 2 GHz / Boost Clock 3 GHz • 11 MB L3 Cache	• Intel Xeon 4109T Silver • 8 Cores, 16 Threads • Base Clock 2 GHz / Boost Clock 3 GHz • 11 MB L3 Cache	No chnage
	RAM 16 GB DDR4 2400MHz	RAM 16 GB DDR4 2400MHz	No change
	Memory: • SQF SSD, M.2 480 GB for Operating System and Applications • Seagate Enterprise 2.5" HDD, 2TB storage, 7000rpm	Memory: • Liteon SSD, M.2 256 GB for Operating System and Applications • Seagate Enterprise 2.5" HDD, 2TB storage, 7000rpm	Similar
	Graphics Card: • Leadtek RTX3060 12GB RAM	Graphics Card: • Leadtek Winfast RTX2070, 8GB RAM	Similar
	Extension Cards: • Magewell Pro Capture AIO 4k; digital 4k framegrabber • Magewell Pro Capture AIO; mixed analog/digital framegrabber • DVP-7013E; analog framegrabber • 96NIC-1G4P-PE-IN2; Intel 4 Port Ethernet Card • 968AD00483; USB to RS422 converter module	Extension Cards: • Magewell Pro Capture AIO 4k; digital 4k framegrabber • Magewell Pro Capture AIO; mixed analog/digital framegrabber • DVP-7013E; analog framegrabber • 96NIC-1G4P-PE-IN2; Intel 4 Port Ethernet Card • 968AD00483; USB to RS422 converter module	No change
RFID Reader	Omnikey 5127CK-Mini, 13.56 MHz	Omnikey 5127CK-Mini, 13.56 MHz	No change
Optical Drive	Lite-On Slim 8X SATA DVD+/-RW Dual Layer	Lite-On Slim 8X SATA DVD+/-RW Dual Layer	No change
RealTime PC	**Mainboard** • AIMB-275G2-00A1E; Advantech Standard Mini ITX Board **CPU** • Intel Core i7-7700T • 4 Cores, 8 Threads • Base clock 2.9 GHz / Boost clock 3.8 GHz • 8 MB Smart Cache **RAM**	**Mainboard** • AIMB-275G2-00A1E; Advantech Standard Mini ITX Board **CPU** • Intel Core i7-7700T • 4 Cores, 8 Threads • Base clock 2.9 GHz / Boost clock 3.8 GHz • 8 MB Smart Cache **RAM**	No change

	• 16 GB DDR4 2400MHz **Extension Cards** • Advantech DMS-IR06 dual port LAN card	• 16 GB DDR4 2400MHz **Extension Cards** • Advantech DMS-IR06 dual port LAN card	
Power Supply	Zippy DHG2-5600V, 600W, 48V-DC	Zippy DHG2-5600V, 600W, 48V-DC	No change
Operating System	• Linux (Yocto Distro Version 3.1, codename "dunfell").	• Linux (Yocto Distro Version 3.1, codename "dunfell").	No change
Surgeon's Monitor	• Connect via HDMI interface • Multi Touch functionality • AG80 anti-glare coating • 32"	• Connect via HDMI interface • Multi Touch functionality • AG80 anti-glare coating • 32"	No change
Small Touch Monitor	• Connected via Display Port interface (DP) • 15.6" Touch display • AG80 anti-glare coating • No DVD-RW drive • No integrated RFID reader • No integrated power On/Off button • No integrated LED indicators • No integrated virtual keyboard	• Connected via Display Port interface (DP) • 15.6" Touch display • AG80 anti-glare coating • No DVD-RW drive • No integrated RFID reader • No integrated power On/Off button • No integrated LED indicators • No integrated virtual keyboard	No change
PowerBox	• XP-Power Custom Design • AC/DC power supplies (5V, 24V, 48V) • Battery with 9000mAh • System can operate without battery	• XP-Power Custom Design • AC/DC power supplies (5V, 24V, 48V) • Battery with 9000mAh • System can operate without battery	No change
Connector Panel	• USB3.0 port for data import • (2) Low Latency Ethernet ports • (3) Standard Ethernet ports • Analog S-Video input • Analog NTSC/PAL Video input • Digital DVI-D input • Digital 4K SDI Video input • Digital 4K HDMI Video input • EM Instrument Adapter Box port (data signals / power) • HDMI output for connecting external monitors • Display Port Video output	• USB3.0 port for data import • (2) Low Latency Ethernet ports • (3) Standard Ethernet ports • Analog S-Video input • Analog NTSC/PAL Video input • Digital DVI-D input • Digital 4K SDI Video input • Digital 4K HDMI Video input • EM Instrument Adapter Box port (data signals / power) • HDMI output for connecting external monitors • Display Port Video output	No change
Operating Principle	The FP8000 Camera enables the calculation of relative spatial relationship of Stryker Navigated Instruments and Trackers which are equipped with IR fiducials by detecting the position of the light center of each fiducial.	The FP8000 Camera enables the calculation of relative spatial relationship of Stryker Navigated Instruments and Trackers which are equipped with IR fiducials by detecting the position of the light center of each fiducial.	No change
Fiducial Types	• Single flashing LEDs • Parallel flashing LEDs • Continuous illuminated LEDs • Reflecting infrared markers which reflect infrared light originating from the FP8000 Camera.	• Single flashing LEDs • Parallel flashing LEDs • Continuous illuminated LEDs • Reflecting infrared markers which reflect infrared light originating from the FP8000 Camera.	No change

	All fiducial types can be tracked in parallel, except for single flashing LEDs.	All fiducial types can be tracked in parallel, except for single flashing LEDs.	
Infrared Sensors	Two 2D sensor arrays arranged at certain fixed distances to each other. Each of the two sensor arrays receives a signal from all illuminated fiducials. This allows for the calculation of the three-dimensional position of the fiducial from the two-dimensional sensors, commonly known for stereo camera systems.	Two 2D sensor arrays arranged at certain fixed distances to each other. Each of the two sensor arrays receives a signal from all illuminated fiducials. This allows for the calculation of the three-dimensional position of the fiducial from the two-dimensional sensors, commonly known for stereo camera systems.	No change
Instrument Communication	Bi-direction IR communication	Bi-direction IR communication	No change
Data Communication	Ethernet Link	Ethernet Link	No change
Pose Calculation	Two dimensional light centroids are calculated based on each of the two sensor images. By triangulating the centroids, the 3D position of the illuminated fiducials can be calculated. Multiple centroids can be acquired at once by illuminating the fiducials in parallel. By matching the 3D positions of the single fiducials to a known instrument geometry the correspondence between measured fiducial positions and fiducials on the instrument can be solved as well as position and orientation of the navigated instruments is calculated.	Two dimensional light centroids are calculated based on each of the two sensor images. By triangulating the centroids, the 3D position of the illuminated fiducials can be calculated. Multiple centroids can be acquired at once by illuminating the fiducials in parallel. By matching the 3D positions of the single fiducials to a known instrument geometry the correspondence between measured fiducial positions and fiducials on the instrument can be solved as well as position and orientation of the navigated instruments is calculated.	No change
Sensor Frame Rate	Up to 500 Hz, applicable to all fiducials	Up to 500 Hz, applicable to all fiducials	No change
Accuracy	Trueness for LED fiducial: • mean Euclidean error <= 150 µm • 95% percentile of Euclidean error < 0.35 mm • Bigger working volume Trueness for reflective fiducial: • mean Euclidean error <= 150 µm • 95% percentile of Euclidean error < =0.35 mm Trueness for single flashing LED fiducial: • $LME_{mean} \leq 70$ µm + 70 µm/m * L, L ≤ 1.5 m	Trueness for LED fiducial: • mean Euclidean error <= 150 µm • 95% percentile of Euclidean error < 0.35 mm • Bigger working volume Trueness for reflective fiducial: • mean Euclidean error <= 150 µm • 95% percentile of Euclidean error < =0.35 mm Trueness for single flashing LED fiducial: • $LME_{mean} \leq 70$ µm + 70 µm/m * L, L ≤ 1.5 m	No change
Color Camera	Compact color video camera (LiveCam) is integrated in the FP8000 camera at a certain fixed position in relation to the infrared sensors in such a way that the axis of the LiveCam is pointing towards the surgical field. Native sensor resolution: • 3840 x 2160 Full HD video stream resolution: • 1920 x 1080	Compact color video camera (LiveCam) is integrated in the FP8000 camera at a certain fixed position in relation to the infrared sensors in such a way that the axis of the LiveCam is pointing towards the surgical field. Native sensor resolution: • 3840 x 2160 Full HD video stream resolution: • 1920 x 1080	No change

Video Out	Integrated color camera video stream over USB 3.0 (5 Gbps)	Integrated color camera video stream over USB 3.0 (5 Gbps)	No change
Infrared Illumination	Provides infrared illumination to illuminate working volume	Provides infrared illumination to illuminate working volume	No change
Power	24V	24V	No change
Working Volume	Pyramidal working volume defined with: X1 ≥ 500 mm X2 ≥ 1400 mm X3 ≥ 1860 mm Y1 ≥ 500 mm Y2 ≥ 1000 mm Y3 ≥ 1560 mm Z1 ≤ 700 mm Z2 ≤ 1300 mm Z3 ≥ 2200 mm 	Pyramidal working volume defined with: X1 ≥ 500 mm X2 ≥ 1400 mm X3 ≥ 1860 mm Y1 ≥ 500 mm Y2 ≥ 1000 mm Y3 ≥ 1560 mm Z1 ≤ 700 mm Z2 ≤ 1300 mm Z3 ≥ 2200 mm 	No change

6.8 Summary of Non-Clinical Testing

The function and performance of the subject devices (i.e., Ortho Guidance Precision Knee Software, Ortho Guidance Express Knee Software, Ortho Guidance Versatile Hip Software, and the Q Guidance System) have been evaluated through non-clinical design verification and validation testing. The results of the evaluation tests demonstrate that the subject devices successfully meet the requirements of their intended use.

Additional testing was performed on the subject devices to ensure they met their design requirements. A summary of the testing and the results are included in the table below.

Item	Summary of Testing
Intended Use/ User Needs	The subject devices were validated with intended users in cadaver labs or simulated use tests to ensure the user needs and intended use requirements were met. All requirements were met and no new issues of safety or effectiveness were raised.
Accuracy	The System is designed to work in the working space with a mean accuracy of 2 mm point and 2° angular axis displacement within the registration zone.
Safety	Verified the effectiveness of all risk controls determined in the device risk analysis. No new questions of safety or effectiveness were raised.
General Requirements and Performance	Verified all components against their design specifications. All requirements were met and no new questions of safety or effectiveness were raised.

Software	Software verification and validation testing was conducted as required by IEC 62304 and FDA guidance on general principles of software validation, January 11, 2002. All requirements were met and no new questions of safety or effectiveness were raised.
Biocompatibility	The subject devices are not intended to be patient contacting.
Electrical Safety	Verified conformance to IEC 60601-1 Ed. 3.2 (2005 + AMD1:2012 + AMD2:2020).
Electromagnetic Compatibility	Verified conformance to IEC 60601-1-2 Ed. 4.1 (2014 + AMD1:2020), CISPR 11 Group 1 Class A.
Shipping	The functionality of the devices after simulated shipping conditions was verified. No new questions of safety or effectiveness were raised.
Sterilization	The subject devices are not intended to be sterilized.

6.9 Summary of Clinical Testing

No clinical testing was performed.

6.10 Conclusion

The subject devices, Ortho Guidance Precision Knee Software, Ortho Guidance Express Knee Software, Ortho Guidance Versatile Hip Software, and the Q Guidance System, perform as intended and are substantially equivalent to their respective predicate device with regard to intended use, design, principles of operation, technology, materials, and performance. No new questions of safety or effectiveness have been raised.