February 13, 2023

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

Re: K223767
Trade/Device Name: Ortho Guidance Precision Knee Software, Ortho Guidance Express Knee Software, Ortho Guidance Versatile Hip Software, Ortho Q Guidance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 15, 2022
Received: December 15, 2022

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 (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,

Jesse Muir -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223767

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

Indications for Use *(Describe)*

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

Ortho Guidance Express Knee Software:
TThe Stryker Ortho Q Guidance System, with the Ortho Guidance Express Knee Software, is intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The system is 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 Ortho Q Guidance System, with the Ortho Guidance Versatile Hip Software, is intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. The system 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 system is 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

Ortho Q Guidance System:
The Stryker Ortho Q Guidance System is intended as an aid for precisely locating anatomical structures in open computer assisted surgery. The 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 skull, vertebra, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

6.0 Submitter Information

6.1 This Premarket Notification is submitted by:

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

6.2 Contact Information

Contact name: Megan Guilbault
Cellular Telephone: (401) 241-6152
Email: megan.guilbault@stryker.com
Date Prepared: December 15, 2022

6.3 Device Name

Table 6-1: 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 Ortho 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

6.4 Predicate Devices

The following are the legally marketed predicate devices for the subject devices included in this Traditional 510(k):

Table 6-2: Predicate Device List

Subject Device	Predicate Device Trade Name	510(k)	Product Code	Manufacturer
Ortho Guidance Precision Knee Software	Stryker OrthoMap Precision Knee 5.0 Software Application	K162341	OLO	Stryker Leibinger GmbH & Co. KG
Ortho Guidance Express Knee Software	Stryker OrthoMap Express Knee 2.0 Software Application	K153240	OLO	Stryker Leibinger GmbH & Co. KG
Ortho Guidance Versatile Hip Software	Stryker OrthoMap Versatile Hip 2.0 Software Application	K162937	OLO	Stryker Leibinger GmbH & Co. KG
Ortho Q Guidance System	Stryker Q Guidance System	K220593	OLO	Stryker Leibinger GmbH & Co. KG

6.5 Device Description

The purpose of this Traditional 510(k) submission is to seek clearance for 3 new software applications and 1 new guidance system. The applications have been created for functionality on the new guidance system in scope of this submission. The subject devices in scope of this submission are outlined in Table 6-1 with the predicate information in Table 6-2. The devices in scope of this submission, Ortho Guidance Precision Knee Software, Ortho Guidance Express Knee Software, Ortho Guidance Versatile Hip Software, and the Ortho 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 Ortho Guidance Precision Knee Software used with Stryker Ortho Q Guidance System is referred as Ortho Guidance Precision Knee System. The Ortho Guidance Express Knee Software used with Stryker Ortho Q Guidance System is referred as Ortho Guidance Express Knee System. The Ortho Guidance Versatile Hip Software used with Stryker Ortho Q Guidance System is referred as Ortho Guidance Versatile Hip System.

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 Ortho Q Guidance System, with the Ortho Guidance Precision Knee Software, is intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The system is 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 Ortho Q Guidance System, with the Ortho Guidance Express Knee Software, is intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The system is 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 Ortho Q Guidance System, with the Ortho Guidance Versatile Hip Software, is intended as a planning and intraoperative guidance system to enable open computer-assisted surgery. The system 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 system is 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 Ortho Q Guidance System

The Stryker Ortho Q Guidance System is intended as an aid for precisely locating anatomical structures in open computer assisted surgery. The 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 skull, vertebra, 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 Stryker OrthoMap Precision Knee 5.0 Software

The technological comparison between the subject device (Ortho Guidance Precision Knee Software) and the predicate device (OrthoMap Precision Knee 5.0 Software) is included in Table 6-3 below. OrthoMap Precision Knee 5.0 Software received clearance per 510(k) number K162341.

Table 6-3: Technological Comparison between the Ortho Guidance Precision Knee Software and Stryker OrthoMap Precision Knee 5.0 Software

Item	**Subject Device:** Ortho Guidance Precision Knee Software	**Predicate Device:** OrthoMap Precision Knee 5.0 Software (K162341)
Platform Compatibility	• Stryker Ortho Q Guidance System	Stryker NAV3i Platform Family including: • Stryker NAV3 Platform • Stryker NAV3i Platform • Stryker NavSuite3 kit Platform
Compatible Operating System	• Linux (Yocto Distro Version 3.1.2, codename “dunfell”).	• Windows 8.1
Workflow Steps	• Patient Preparation • System Set-up • Patient Registration • Analyze Initial Alignment	• Patient Preparation • System Set-up • Patient Registration • Analyze Initial Alignment

	• Size and Position Implant • Resect Bones • Analyze Trial Implant • Analyze Final Implant	• Size and Position Implant • Resect Bones • Analyze Trial Implant • Analyze Final Implant
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 optical active sensing technology: Infrared light emitted by diodes placed in specific locations on navigated surgical instruments is sensed by a camera array (navigation camera) on the platform, which allows for computation of the spatial information
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
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 orange highlighted button indicates the selected function.
Intended Use Environment	Operating Room (OR)	Operating Room (OR)
Intended Users	Trained clinical staff	Trained clinical staff.
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.
User Interface	• Surgeon's Monitor • Small Touch Monitor • Mouse • Buttons on active optical instruments	• Monitor • I/O Tablet • Mouse • Buttons on active optical instruments

6.7.2 Technological Comparison between the Ortho Guidance Express Knee Software and Stryker OrthoMap Express Knee 2.0 Software

The technological comparison between the subject device (Ortho Guidance Express Knee Software) and the predicate device (OrthoMap Express Knee 2.0 Software) is included in Table 6-4 below. OrthoMap Express Knee 2.0 Software received clearance per 510(k) number K153240.

Table 6-4: Technological Comparison between the Ortho Guidance Express Knee Software and Stryker OrthoMap Express Knee 2.0 Software

Item	**Subject Device:** Ortho Guidance Express Knee Software	**Predicate Device:** OrthoMap Express Knee 2.0 Software (K153240)
Platform Compatibility	• Stryker Ortho Q Guidance System	Stryker NAV3i Platform Family including: • Stryker NAV3 Platform • Stryker NAV3i Platform • Stryker NavSuite3 kit Platform
Compatible Operating System	• Linux (Yocto Distro Version 3.1.2, codename "dunfell").	• Windows 8.1
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 (femur) • Navigation (femur) • Patient Registration (tibia) • Navigation (tibia)
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 optical active sensing technology: Infrared light emitted by diodes placed in specific locations on navigated surgical instruments is sensed by a camera array (navigation camera) on the platform, which allows for computation of the spatial information
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
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 orange highlighted button indicates the selected function.
Intended Use Environment	Operating Room (OR)	Operating Room (OR)
Intended Users	Trained clinical staff	Trained clinical staff
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.
User Interface	• Surgeon's Monitor • Small Touch Monitor	• Monitor • I/O Tablet

	• Mouse • Buttons on active optical instruments	• Mouse • Buttons on active optical instruments
Tracking Signal Output	Visual and auditory	Visual and auditory

6.7.3 Technological Comparison between the Ortho Guidance Versatile Hip Software and Stryker OrthoMap Versatile Hip 2.0 Software

The technological comparison between the subject device (Ortho Guidance Versatile Hip Software) and the predicate device (OrthoMap Versatile Hip 2.0 Software) is included in Table 6-5 below. OrthoMap Versatile Hip 2.0 Software received clearance per 510(k) number K162937.

Table 6-5: Technological Comparison between the Ortho Guidance Versatile Hip Software and Stryker OrthoMap Versatile Hip 2.0 Software

Item	**Subject Device:** Ortho Guidance Versatile Hip Software	**Predicate Device:** OrthoMap Versatile Hip 2.0 Software (K162937)
Platform Compatibility	• Stryker Ortho Q Guidance System	Stryker NAV3i Platform Family including: • Stryker NAV3 Platform • Stryker NAV3i Platform • Stryker NavSuite3 kit Platform
Operating System	• Linux (Yocto Distro Version 3.1.2, codename “dunfell”).	• Windows 8.1
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
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 optical active sensing technology: Infrared light emitted by diodes placed in specific locations on navigated surgical instruments is sensed by a camera array (navigation camera) on the platform, which allows for computation of the spatial information
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
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.	• 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.	• The information of the software is displayed on a monitor. • On the monitor, the orange highlighted button indicates the selected function.
Intended Use Environment	Operating Room (OR)	Operating Room (OR)
Intended Users	Trained clinical staff	Trained clinical staff.
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.
User Interface	• Surgeon's Monitor • Small Touch Monitor • Mouse • Buttons on active optical instruments	• Monitor • I/O Tablet • Mouse • Buttons on active optical instruments
Tracking Signal Output	Visual and auditory	Visual and auditory

6.7.4 Technological Comparison between the Ortho Q Guidance System and Stryker Q Guidance System

The technological comparison between the subject device (Ortho Q Guidance System) and the predicate device (Stryker Q Guidance System) is included in Table 6-6 below. Stryker Q Guidance System received clearance per 510(k) number K220593.

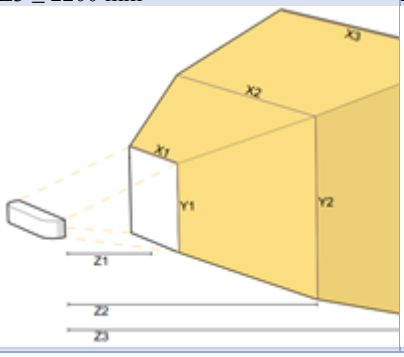
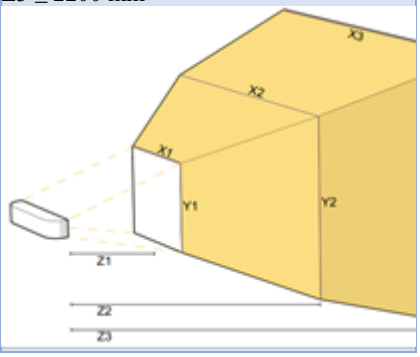
Table 6-6: Technological Comparison between the Ortho Q Guidance System and Stryker Q Guidance System

Item	**Subject Device:** Ortho Q Guidance System	**Predicate Device:** Stryker Q Guidance System (K220593)
Operating Principle	The Ortho Q Guidance System runs Stryker Ortho Guidance Software applications on a Linux based dual PC system. For patient data import/export, the system provides standard state-of-the-art storage media and network interfaces. For video import the system provides standard state-of-the-art video interface to capture live video. The Ortho Q Guidance System offers an active optical localization device (FP8000 Camera) that enables the calculation of relative spatial relationship of Stryker active optical instruments and trackers, which are equipped with LEDs by detecting the position of the light center of each single flashing LED. The Stryker Navigation Application Software is operated via active optical instruments during surgery.	The Q Guidance System runs Stryker Spine Guidance 4.0 Software on a Linux based dual PC system. For patient data import/export, the system provides standard state-of-the-art storage media and network interfaces. For video import the system provides standard state-of-the-art video interface to capture live video. The Q Guidance System offers an active and passive optical localization device (FP8000 Camera) that enables the calculation of relative spatial relationship of Stryker active optical instruments and trackers, which are equipped with LEDs, and passive optical instruments, which are equipped with reflective fiducials by detecting the position of the light center of each single flashing LED or the center of the reflective fiducials. The Spine Guidance 4.0 Software can be operated via active optical instruments during surgery

		or via the touch monitors, mouse, and keyboard.
Dimensions	Outer dimensions: • Length x Width x Height: 770 x 700 x 1950 mm • Weight: 64 kg	Outer dimensions: • Length x Width x Height: 950 x 720 x 1950 mm • Weight: 265 kg
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% • Atmospheric pressure: 70 kPa – 106 kPa	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% • Atmospheric pressure: 70 kPa – 106 kPa
WiFi Connectivity	TP-Link Archer T9UH, WiFi-USB - Adapter/Dongle	TP-Link Archer T9UH, WiFi-USB - Adapter/Dongle
Cable Guard Cart Castors	Spatula front mounted design	Spatula front mounted design
Keyboard and Mouse	• Man & Machine Petite Mouse Medical grade mini mouse; silicon 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
Application PC	Mainboard: MB-815-00A1E; Advantech Standard Server Board	Mainboard: MB-815-00A1E; Advantech Standard Server Board
	• 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
	RAM 16 GB DDR4 2400MHz	RAM 16 GB DDR4 2400MHz
	Memory: • Liteon SSD, M.2 256 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
	Graphics Card: • NVIDIA RTX 2070 with 8 GByte video memory	Graphics Card: • Leadtek Winfast RTX2070, 8GB RAM
	Extension Cards: • Magewell Pro Capture AIO 4k; digital 4k framegrabber • Magewell Pro Capture AIO; mixed analog/digital framegrabber	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	• DVP-7013E; analog framegrabber • 96NIC-1G4P-PE-IN2; Intel 4 Port Ethernet Card • 968AD00483; USB to RS422 converter module
RFID Reader	Omnikey 5127CK-Mini, 13.56 MHz	Omnikey 5127CK-Mini, 13.56 MHz
Optical Drive	Lite-On Slim 8X SATA DVD+/-RW Dual Layer	Lite-On Slim 8X SATA DVD+/-RW Dual Layer
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** • 16 GB DDR4 2400MHz **Extension Cards** • Advantech DMS-IR06 dual port LAN card	**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** • 16 GB DDR4 2400MHz **Extension Cards** • Advantech DMS-IR06 dual port LAN card
Power Supply	100-240 VAC, 50-60 Hz, 6.9-2.9 A	Zippy DHG2-5600V, 600W, 48V-DC
Operating System	• Linux (Yocto Distro Version 3.1.2, codename “dunfell”).	• Linux (Yocto Distro Version 3.1.2, codename “dunfell”).
Surgeon’s Monitor	• Connect via HDMI interface • Multi Touch functionality • AG80 anti-glare coating • 27”	• Connect via HDMI interface • Multi Touch functionality • AG80 anti-glare coating • 32”
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
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
Connector Panel	• USB3.0 port for data import • (2) Low Latency Ethernet ports • Analog S-Video input • Digital DVI-D input • Digital 4K SDI Video input • Digital 4K HDMI Video input • HDMI output for connecting external monitors	• 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
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.
Fiducial Types	• Single flashing LEDs • Parallel flashing LEDs • Continuous illuminated LEDs • Reflecting infrared markers which reflect infrared light originating from the FP8000 Camera. All fiducial types can be tracked in parallel, except for single flashing LEDs.	• Single flashing LEDs • Parallel flashing LEDs • Continuous illuminated LEDs • Reflecting infrared markers which reflect infrared light originating from the FP8000 Camera. 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
Instrument Communication	Bi-direction IR communication	Bi-direction IR communication
Data Communication	Ethernet Link	Ethernet Link
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.
Sensor Frame Rate	Up to 500 Hz, applicable to all fiducials	Up to 500 Hz, applicable to all fiducials
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 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: • $LME_{mean} \leq 70\ \mu m + 70\ \mu m/m * L, L \leq 1.5\ m$	Trueness for single flashing LED fiducial: • $LME_{mean} \leq 70\ \mu m + 70\ \mu m/m * L, L \leq 1.5\ m$
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
Video Out	Integrated color camera video stream over USB 3.0 (5 Gbps)	Integrated color camera video stream over USB 3.0 (5 Gbps)
Infrared Illumination	Provides infrared illumination to illuminate working volume	Provides infrared illumination to illuminate working volume
Power	24V	24V
Working Volume	Pyramidal working volume defined with: X1 ≥ 500 mm X2 ≥ 1400 mm X3 ≥ 1860 mm Y1 ≥ 500 mm Y2 ≥ 1030 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 ≥ 1030 mm Y3 ≥ 1560 mm Z1 ≤ 700 mm Z2 ≤ 1300 mm Z3 ≥ 2200 mm 

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 Ortho 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.

<table>
<tr><th>Item</th><th>Summary of Testing</th></tr>
<tr><td>Intended Use/ User Needs</td><td>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.</td></tr>
<tr><td>Accuracy</td><td>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. The 95th percentile of the point displacement is ≤ 3 mm and ≤ 3° for angular axis displacement within the registration zone.
<table>
<tr><th></th><th>Positional Displacement (mm)</th><th>Trajectory Angle Displacement (degrees)</th></tr>
<tr><td>99% Confidence Interval (Upper)</td><td>2.60</td><td>1.78</td></tr>
<tr><td>Mean</td><td>1.32</td><td>0.73</td></tr>
<tr><td>Standard Deviation</td><td>0.52</td><td>0.43</td></tr>
</table></td></tr>
<tr><td>Safety</td><td>Verified the effectiveness of all risk controls determined in the device risk analysis. No new questions of safety or effectiveness were raised.</td></tr>
<tr><td>General Requirements and Performance</td><td>Verified all components against their design specifications. All requirements were met and no new questions of safety or effectiveness were raised.</td></tr>
<tr><td>Software</td><td>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.</td></tr>
<tr><td>Biocompatibility</td><td>The subject devices are not intended to be patient contacting.</td></tr>
<tr><td>Electrical Safety</td><td>Verified conformance to IEC 60601-1: 2005, COR. 1:2006, COR. 2:2007, AMD 1:2012 (equivalent to IEC 60601-1:2012 Reprint).</td></tr>
<tr><td>Electromagnetic Compatibility</td><td>Verified conformance to IEC 60601-1-2: 2014, CISPR 11 Group 1, Class A requirements as well as additional testing to verify compatibility with RFID devices operating in the 125 - 134 kHz and 13.56 MHz frequency band.</td></tr>
<tr><td>Shipping</td><td>The functionality of the devices after simulated shipping conditions was verified. No new questions of safety or effectiveness were raised.</td></tr>
<tr><td>Sterilization</td><td>The subject devices are not intended to be sterilized.</td></tr>
</table>

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 Ortho 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.