K103400 MAR - 7 2011

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

Submitter Information	
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Establishment Registration Number	3007582679
Name of contact person	Lilian Eckert
Date prepared	17 November 2010
Name of device	
Trade or proprietary name	FluoroMap Computer Assisted Surgery System
Common or usual name	FluoroMap System
Classification name	Orthopedic stereotaxic instrument and Picture archiving and communications system
Classification panel	Orthopedic and Radiology
Regulation	§882.4560
Product Code(s)	OLO and LLZ
Legally marketed device(s) to which equivalence is claimed	VectorVision trauma from BrainLAB AG, K062358 TenZing System from Mazor Surgical Technologies Ltd., K102130 Gamma3 Lag Screw from Stryker Trauma GmbH, K020677 Gamma3 Trochanteric Nail from Stryker Trauma GmbH, K032244
Reason for 510(k) submission	Traditional 510(k) Notification
Device description	The FluoroMap System is designed as a computer assisted surgical planning device to assist the surgeon in proximal femur fracture surgery. The FluoroMap System provides static localization information derived through image processing of intra-operatively acquired X-ray images, by superposition of virtual implants and instruments onto those X-ray images. The FluoroMap System consists of the FluoroMap Software, the FluoroDisc and the Closed Tube Clip. The Closed Tube Clip is a device which contains a radiolucent body with integrated metal marker spheres. The Closed Tube Clip is attached to the implant system of the Gamma3 Nail. The FluoroDisc

	is a device which contains a radiolucent plate with integrated metal marker spheres. It is attached to a standard C-arm, an intra-operative mobile 2D X-ray imaging device. The FluoroMap Software is a surgery planning system which recognizes the metal marker spheres of the FluoroDisc and the Close Tube Clip and performs a registration of the X-ray images to localize the position of the implant system, e.g. the Gamma3 Nail system. The FluoroMap Software overlays virtual implants and instruments onto the X-ray images and provides visual and numerical information to assist the surgeon in selecting the appropriate implant and to position it precisely.
Intended use of the device	FluoroMap is a computer controlled stereotaxic image guided surgery system. It provides static localization information derived from image processing of intra-operatively acquired X-ray images, by superposition of virtual implants and instruments onto those X-ray images.
Indications for use	FluoroMap assists the surgeon to determine the needed size and position of orthopedic implants during proximal femur fracture surgery using the Stryker Gamma3 Nail system. The system should be operated only by trained personnel such as surgeons and clinic staff.

Summary of the technological characteristics of the device compared to the predicate device 1

Characteristic	Subject Device FluoroMap	Predicate device 1 VectorVision trauma, BrainLAB AG, K062358
Intended Use / Indication for Use Statement	Intended Use: FluoroMap is a computer controlled stereotaxic image guided surgery system. It provides static localization information derived from image processing of intra-operatively acquired X-ray images, by superposition of virtual implants and instruments onto those X-ray images. Indications: FluoroMap assists the surgeon to determine the needed size and position of orthopedic implants during proximal femur fracture surgery using the Stryker Gamma3 Nail system. The system should be operated only by trained personnel such as surgeons and clinic staff.	BrainLAB VectorVision trauma is intended to be a pre- and intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's pre- or intraoperative image data being processed by a VectorVision workstation. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a bone structure like tubular bones, pelvic, calcaneus and talus, or vertebra, can be identified relative to a CT, fluoroscopic, X-ray or MR based model of the anatomy.
Intended Patient Population	Patients undergoing orthopedic surgery	Patients undergoing orthopedic surgery
Surgical Approach	Orthopedic surgery, specifically at the proximal femur	Orthopedic surgery, specifically surgery at tubular bones, pelvic, calcaneus and talus, or vertebra
Intended Users	Surgeons and clinical staff	Surgeons and clinical staff

Operational Environment	Surgical suite	Surgical suite
Primary Device Function	Assistance in planning and positioning of orthopedic implants using intra-operative X-ray images	Assistance in planning and positioning of orthopedic implants using intra-operative X-ray images
Main System Components	• Software • Reference device for C-arm • Reference device for instrumentation	• Software • Reference device for C-arm • Reference device for instrumentation • Reference system for patient
User Interface	Computer and monitor	Computer and monitor
Bench Testing	Accuracy testing of implant positioning in simulated use scenarios using cadavers, saw bones and computer simulation; system accuracy of 2 mm	Unknown, expected to be similar accuracy tests with similar results
Conformance to Recognized Consensus Standards	Compliance with standards in regard to risk management, usability, software, sterilization, biocompatibility, packaging, development process and quality system, see section 1.11	Unknown
Body Contact and Use	Reference device for instrumentation (Closed Tube Clip) has patient contact	Reference device for instruments and reference device for patient have body contact
Sterile, Single-use	Reference device for instrumentation (Closed Tube Clip) is delivered sterile and as a single use product	Parts of the reference device (infra-red reflectors) are delivered sterile and are single use products

Summary of the technological characteristics of the device compared to the predicate device 2

Characteristic	Subject Device FluoroMap	Predicate device 2 TenZing System, Mazor, K102130
Intended Use / Indication for Use Statement	Intended Use: FluoroMap is a computer controlled stereotaxic image guided surgery system. It provides static localization information derived from image processing of intra-operatively acquired X-ray images, by superposition of virtual implants and instruments onto those X-ray images. Indications: FluoroMap assists the surgeon to determine the needed size and position of orthopedic implants during proximal femur fracture surgery using the Stryker Gamma3 Nail system. The system should be operated only by trained personnel such as surgeons and clinic staff.	The TenZing System is a combination of the SpineAssist system and C-InSight System, allowing the C-InSight application to run on the SpineAssist Workstation: The SpineAssist System is indicated for precise positioning of surgical instruments or implants during general spinal surgery. The SpineAssist System may be used in either open or percutaneous procedures. The C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly in orthopedic applications.
Intended Patient Population	Patients undergoing orthopedic surgery	Patients undergoing orthopedic surgery
Surgical Approach	Orthopedic surgery, specifically at the proximal femur	Orthopedic surgery, specifically at the spine

Intended Users	Surgeons and clinical staff	Surgeons and clinical staff
Operational Environment	Surgical suite	Surgical suite
Primary Device Function	Assistance in planning and positioning of orthopedic implants using intra-operative X-ray images	Assistance in planning and positioning of orthopedic implants using intra-operative X-ray images
Main System Components	• Software • Reference device for C-arm • Reference device for instrumentation	• Software • Reference device for C-arm • Reference system for patient • Motorized guide
User Interface	Computer and monitor	Computer and monitor
Bench Testing	Accuracy testing of implant positioning in simulated use scenarios using cadavers, saw bones and computer simulation; system accuracy of 2 mm	Unknown, expected to be similar accuracy tests with similar results
Body Contact and Use	Reference device for instrumentation, Closed Tube Clip, has patient contact	Reference device for patient and motorized guide have body contact

Summary of the technological characteristics of the device compared to the predicate device 3

Characteristic	Subject Device FluoroMap	Predicate device 3 Gamma3 Lag Screw K020677
Intended Use / Indication for Use Statement	Intended Use: FluoroMap is a computer controlled stereotaxic image guided surgery system. It provides static localization information derived from image processing of intra-operatively acquired X-ray images, by superposition of virtual implants and instruments onto those X-ray images. Indications: FluoroMap assists the surgeon to determine the needed size and position of orthopedic implants during proximal femur fracture surgery using the Stryker Gamma3 Nail system. The system should be operated only by trained personnel such as surgeons and clinic staff.	Indications for Use: The Gamma 3 Lag Screw is intended to be used with both the Long Length Dyax Nail and the Trochanteric Dyax Nail. Intended Use for the Long Length Dyax Nail The product is intended to be used in fixation of femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intracondylar notch. Fracture types include basilar neck, intertrochanteric, subtrochanteric fractures and femoral shaft fractures. These femoral fractures may occur as a result of trauma, non-union, mal-union, pathological fractures, and impending pathological fractures. Intended Use for the Trochanteric Dyax Nail: The product is intended for use in stabilizing various types of intertrochanteric fractures of the femur.

Summary of the technological characteristics of the device compared to the predicate device 4		
Characteristic	**Subject Device FluoroMap**	**Predicate device 4 Gamma3 Trochanteric Nail K032244**
Intended Use / Indication for Use Statement	Intended Use: FluoroMap is a computer controlled stereotaxic image guided surgery system. It provides static localization information derived from image processing of intra-operatively acquired X-ray images, by superposition of virtual implants and instruments onto those X-ray images. Indications: FluoroMap assists the surgeon to determine the needed size and position of orthopedic implants during proximal femur fracture surgery using the Stryker Gamma3 Nail system. The system should be operated only by trained personnel such as surgeons and clinic staff.	Indications for Use: The Gamma 3 Lag Screw is intended to be used with both the Long Length Dyax Nail and the Trochanteric Dyax Nail. Intended Use for the Long Length Dyax Nail The product is intended to be used in fixation of femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intracondylar notch. Fracture types include basilar neck, intertrochanteric, subtrochanteric fractures and femoral shaft fractures. These femoral fractures may occur as a result of trauma, non-union, mal-union, pathological fractures, and impending pathological fractures. Intended Use for the Trochanteric Dyax Nail: The product is intended for use in stabilizing various types of intertrochanteric fractures of the femur.

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
Accuracy	2 mm accuracy (maximal deviation between displayed and actual implant position)	Accuracy target met with statistical significance in cadaveric test, saw bones tests and computer simulation
Usability	Meet all specified user needs, comply with usability standard IEC 62366:2007	In cadaveric test with simulated use case scenarios the specified user needs were validated and the system was usable in accordance with usability standards
Safety	Perform risk analysis, indentify risk mitigation measures and verify that the measures are effective, comply with risk management standard ISO 14971:2007	All safety measures are verified to be effective
Recognized Consensus Standards	Comply with the following sterility and biocompatibility standards: AAMI/ANSI/ISO 11737-1:2006,	The Closed Tube Clip which has body contact and which is delivered sterile is

	AAMI/ANSI/ISO 11737-2:2009, AAMI/ANSI/ISO 11607-1, AAMI/ ANSI/ISO 11137-1:2006/(R) 2010, AAMI/ANSI/ISO 11137-2:2006, AAMI/ANSI/ISO 10993-1:2009, AAMI/ANSI/ISO 10993-5:2009, AAMI/ANSI/ISO 10993-10:2010, AAMI/ANSI/ISO 10993-18:2005	tested to comply with all specified standards

Comparative Performance Information Summary			
Characteristic	**Requirement**	**New Device**	**Predicate Device**
Accuracy	2 mm (maximal deviation between displayed and actual implant position)	All accuracy tests passed the 2 mm accuracy target with statistical significance	The TenZing System was tested in pre-clinical and clinical trials proving that an accuracy of 2 mm is reached (see Attachment 3-B). For the VectorVision trauma system a similar accuracy is expected.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

No clinical tests have been conducted.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The performance tests demonstrate that an accuracy of 2 mm is reached in simulated clinical scenarios. The system fulfills all usability needs proven in simulated use case scenarios. All system safety measures are effective and all components pass safety testing.

All requirements of the stated standards are met. The intended use and technological characteristics of the FluoroMap System are similar to the predicate devices.

According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the FluoroMap System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Corporation
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Senior Regulatory Affairs Specialist
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79111 Freiburg, Germany

MAR - 7 2011

Re: K103400
Trade/Device Name: FluoroMap Computer Assisted Surgery System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: February 11, 2011
Received: February 14, 2011

Dear Ms. Eckert:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number (if known): K103400

Device Name: FluoroMap

Intended Use:

FluoroMap is a computer controlled stereotaxic image guided surgery system. It provides static localization information derived from image processing of intra-operatively acquired X-ray images, by superposition of virtual implants and instruments onto those X-ray images.

Indications:

FluoroMap assists the surgeon to determine the needed size and position of orthopedic implants during proximal femur fracture surgery using the Stryker Gamma3 Nail system.

The system should be operated only by trained personnel such as surgeons and clinic staff.

Prescription Use (Part 21 CFR 801 Subpart D) ___X___ AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103400