K120867

510(K) SUMMARY

SEP 20 2012

A. Submitter Information

Manufacturer:	Medos International, Sárl Chemin-Blanc 38 Le Locle, CH-NE 2400, Switzerland
Submitter:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02767
Contact Person:	Laura Bleyendaal 325 Paramount Drive Raynham, MA 02767
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B. Date Prepared May 2012

C. Device Name

Trade/Proprietary Name:	VIPER® and EXPEDIUM® navigated instruments
Common/Usual Name:	Stereotaxic Instrument
Device Classification and Regulatory Class:	Class II, per 21 CFR § 882.4560
Device Product and Panel Code:	OLO; Orthopedic

D. Predicate Device Name

Trade name: Brainlab VectorVision Fluoro 3D system (K070106)

E. Device Description

The VIPER® and EXPEDIUM® navigated instruments are surgical instruments, for use in the implantation of VIPER® and EXPEDIUM® pedicle screws, which have been modified for use with Brainlab image guided surgery (IGS) hardware and software. The navigated instrument shafts mate with modified handles containing tracking arrays with Brainlab proprietary designs, or contain a dedicated interface for receiving a Brainlab owned tracking array. The passive tracking arrays enable the VIPER® and EXPEDIUM® navigated instruments to be tracked by the Brainlab system to virtual computer image space on a patient's preoperative or intra-operative 2D or 3D image data.

F. Indications for Use

The VIPER® and EXPEDIUM® navigated instruments are image guided surgical instruments for use in the implantation of VIPER® and EXPEDIUM® pedicle screws in an open or percutaneous approach. The navigated instruments are designed for use only with Brainlab Image Guided Surgery hardware and software. The navigated instruments are indicated for any medical condition in which the use of stereotactic surgery may be appropriate, where the use of the VIPER® and/or EXPEDIUM® Spine Systems is indicated and where reference to a rigid anatomical structure, such as the pelvis or a vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.

G. Summary of Similarities and Differences in Technological Characteristics, Performance and Indications for Use

	VIPER® and EXPEDIUM® navigated instruments	Predicate Brainlab VectorVision Fluoro 3D system (K070106)
Indications for Use	The VIPER® and EXPEDIUM® navigated instruments are image guided surgical instruments for use in the implantation of VIPER® and EXPEDIUM® pedicle screws in an open or percutaneous approach. The navigated instruments are designed for use only with Brainlab Image Guided Surgery hardware and software. The navigated instruments are indicated for any medical condition in which the use of stereotactic surgery may be appropriate, where the use of the VIPER® and/or EXPEDIUM® Spine Systems is indicated and where reference to a rigid anatomical structure, such as the pelvis or a vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.	Brainlab VectorVision fluoro3D is intended as an intra-operative 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 preoperative or intra-operative 2D or 3D image data. VectorVision fluoro3D enables computer–assisted navigation of medical image data which can either be acquired preoperatively or intra-operatively by an appropriate image acquisition system. The software offers screw implant size planning and navigation on rigid bone structures with precalibrated and individually-calibrated surgical tools. 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, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.
Passive Marker/ Array	Yes; same tracking arrays as predicate instruments	Yes
Instruments	Awls, Probes, Taps, Screwdrivers and Jamshidi Needle	Awls, Probes, Chisels and Drill Guide with Trocar Insert
Sterility	Non-sterile	Non-sterile
Computer Aided	Yes	Yes
Reusable	Yes	Yes
Compatible Brainlab Navigation Software	Navigation Software VectorVision Spine (Version 5.5 and 5.6) Navigation Software Kolibri Spine (Version 2.0) Navigation Software VectorVision Trauma (Version 2.6) Navigation Software VectorVision Fluoro3D (Version 1.6 and 2.0) Navigation Software Spine & Trauma iCT (Version 1.0) Navigation Software Trauma (Version 3.0) Navigation Software Spine & Trauma 3D (Version 2.0)	Navigation Software VectorVision Spine (Version 5.5 and 5.6) Navigation Software Kolibri Spine (Version 2.0) Navigation Software VectorVision Trauma (Version 2.6) Navigation Software VectorVision Fluoro3D (Version 1.6 and 2.0) Navigation Software Spine & Trauma iCT (Version 1.0) Navigation Software Trauma (Version 3.0) Navigation Software Spine & Trauma 3D (Version 2.0)

H. Materials

The VIPER® and EXPEDIUM® navigation handles are manufactured from stainless steels 630, 431, 301, 303, 316, Silicone Elastosil R 401/80, Radel® and titanium nitride. The navigated instrument shafts are manufactured from stainless steels 17-4PH, custom 455, custom 465, 18-8, 316, 316L, 420, and aluminum 6061-T6.

I. Performance Data

Verification and validation of the VIPER® and EXPEDIUM® navigated instruments integration into the Brainlab Navigation Software was performed.

J. Conclusion

The VIPER® and EXPEDIUM® navigated instruments intended use, principles of operation and technological characteristics are substantially equivalent to those of the predicate Brainlab instruments.

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

SEP 20 2012

Medos International Sarl
% Johnson and Johnson (Depuy Spine)
Ms. Laura Bleynedaal
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K120867
Trade/Device Name: VIPER® and EXPEDIUM® navigated instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HAW
Dated: September 04, 2012
Received: September 05, 2012

Dear Ms. Bleynedaal:

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.

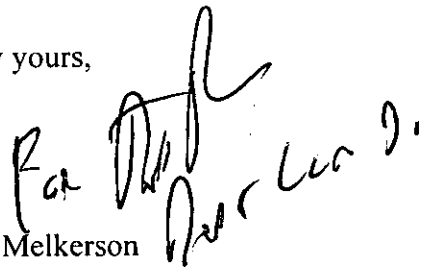
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

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,



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): K120867

Device Name: VIPER® and EXPEDIUM® navigated instruments

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___

(Part 21 CFR § 801 Subpart D) (21 CFR § 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mxm

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

510(k) Number K120867