DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Medos International, SARL
% Laura Bleyendaal
Senior Regulatory Affairs Specialist
DePuy Synthes
325 Paramount Drive
Raynham, Massachusetts 02767

September 14, 2017

Re: K170937
Trade/Device Name: VIPER PRIME navigated inserter
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 5, 2017
Received: May 8, 2017

Dear Laura Bleyendaal:

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 contact the Division of Industry and Consumer Education (DICE) 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. 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 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 Industry and Consumer Education (DICE) 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170937

Device Name
VIPER PRIME™ navigated inserter

Indications for Use *(Describe)*
The VIPER PRIME navigated inserter is a navigated instrument for insertion of VIPER PRIME screws in open or percutaneous procedures. The VIPER PRIME navigated inserter is indicated for use in spinal surgical procedures, in which:
• use of the VIPER System is indicated,
• use of stereotactic surgery may be appropriate, and
• where reference to a rigid anatomical structure, such as the pelvis or a vertebrae 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 using a navigation system which includes universal tracking arrays supplied by the navigation manufacturer. These procedures include but are not limited to spinal fusion. The VIPER PRIME navigated inserter requires manual calibration.

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.

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510(k) Summary

A. Submitter Information

510(k) Sponsor:	Medos International, SARL
Contact Person:	Laura Bleyendaal DePuy Synthes 325 Paramount Drive Raynham, MA 02767
Telephone number:	(508) 828-3267
Fax number:	(508) 828-3797
Email:	Lbleyend@its.jnj.com

B. Date Prepared

September 13, 2017

C. Device Name

Trade/Proprietary Name:	VIPER PRIME™ navigated inserter
Common/Usual Name:	Orthopedic stereotaxic instrument
Device Classification and Regulation:	Class II per 21 CFR § 882.4560
Classification Product and Panel Code:	OLO; Orthopedic

D. Predicate Device Name

Primary Predicate Device:
Synthes Navigable Pedicle Preparation Instruments (K122211)

Reference Devices:
Stryker SpineMap® 3D Navigation System (K141941)
Medtronic StealthStation® System (K133444)
Brainlab (K070106)

E. Device Description

The VIPER PRIME™ navigated inserter is a reusable manual screwdriver for insertion of the VIPER PRIME screws of the VIPER® System in open and percutaneous procedures. The VIPER PRIME navigated inserter also features attachment sites for universal tracking arrays supplied by the navigation manufacturer to enable use with the respective spine navigation system. The VIPER PRIME navigated inserter must be manually calibrated with the third-party navigation system.

F. Indications for Use

The VIPER PRIME navigated inserter is a navigated instrument for insertion of VIPER PRIME screws in open or percutaneous procedures. The VIPER PRIME navigated inserter is indicated for use in spinal surgical procedures, in which:

- use of the VIPER System is indicated,
- use of stereotactic surgery may be appropriate, and
- where reference to a rigid anatomical structure, such as the pelvis or a vertebrae 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 using a navigation system which includes universal tracking arrays supplied by the navigation manufacturer.

These procedures include but are not limited to spinal fusion. The VIPER PRIME navigated inserter requires manual calibration.

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

The technological characteristics, including materials, design and performance of the VIPER PRIME navigated inserter are consistent with those of the primary predicate device. In brief, both the primary predicate and subject devices are indicated for use in open or percutaneous spinal surgical procedures in which the use of stereotactic surgery may be appropriate. The Synthes Navigable Pedicle Preparation instruments include awls, probes, taps, screwdrivers, a dilator, a guide tube and a pedicle access cannula while the VIPER PRIME navigated inserter is a screwdriver. The Synthes Navigable Pedicle Preparation instruments are manufactured from surgical grade metals, silicone and polyetheretherketone (PEEK), while the VIPER PRIME navigated inserter is manufactured from stainless steel, titanium alloy (Ti-6Al-4V) and polyphenylsulfone (RADEL®). Both the Synthes Navigable Pedicle Preparation instruments and VIPER PRIME navigated inserter feature attachment sites for universal tracking arrays supplied by the navigation manufacturer to enable use with the respective spine navigation system. The VIPER PRIME navigated inserter requires manual calibration and similarly, the Synthes

Navigable Pedicle Preparation instruments include instruments which may be manually calibrated with the spine navigation systems.

H. Materials

The VIPER PRIME navigated inserter is manufactured from stainless steel, titanium alloy (Ti-6Al-4V) and RADEL®.

I. Performance Data

Non-clinical sawbones testing was conducted to confirm device performance for the intended use. The testing consisted of assembly of the VIPER PRIME navigated inserter with the third party universal tracking arrays, manual calibration and navigated insertion of VIPER PRIME screws in a sawbones model. Final screw position in the software was confirmed using a second imaging modality.

J. Conclusion

The indications for use and intended use of the VIPER PRIME navigated inserter are consistent with those of the primary predicate device. The technological characteristics of the VIPER PRIME navigated inserter in terms of design, materials and performance are consistent with those of the predicate device. The VIPER PRIME navigated inserter is substantially equivalent to the primary predicate device.