May 5, 2022

MEDOS International SARL
Nicole Aeschbacher
Regulatory Affairs Specialist
Chemin-Blanc 38
Le Locle, 2400
Switzerland

Re: K212756
Trade/Device Name: Discectomy Navigation Ready Instruments and Universal Navigation Adaptor Set
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 23, 2022
Received: April 4, 2022

Dear Nicole Aeschbacher:

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,

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)*

K212756

Device Name

Discectomy Navigation Ready Instruments and Universal Navigation Adaptor Set

Indications for Use *(Describe)*

Discectomy Navigation Ready Instruments

The Discectomy Navigation Ready Instruments when used with the compatible Universal Navigation Adaptor Set are intended to assist the surgeon in locating anatomical structures to facilitate disc space preparation, including discectomy or bony resection. These are indicated for use in surgical spinal procedures, in which:

• the use of stereotactic surgery may be appropriate, and

• 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 and associated navigation arrays.

These procedures include but are not limited to spinal fusion. The Discectomy Navigation Ready instruments can be pre-calibrated with the Brainlab Navigation System.

Universal Navigation Adaptor Set:

The Universal Navigation Adaptor Set (UNAS) is intended for use with the compatible DePuy Synthes Navigation Ready Instruments to assist the surgeon in locating anatomical structures in either open or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which:

• the use of stereotactic surgery may be appropriate, and

• 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 and associated tracking arrays.

These procedures include but are not limited to spinal fusion. The DePuy Synthes Navigation Ready Instrument, when used with UNAS, can be pre-calibrated and/or manually calibrated with the Brainlab Navigation System, where other navigation systems require manual calibration and tracking arrays supplied by the navigation system manufacturer.

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."*

# 510(k) Summary

## A. Submitter Information

**510(k) Sponsor:** Medos International, SARL

**Contact Person:** Nicole Aeschbacher, Regulatory Affairs Specialist
Eimattstrasse 3
4436 Oberdorf
Switzerland

Telephone: +41 61 965 61 18
Fax: +41 61 965 66 16
Email: naeschba@its.jnj.com

## B. Date Prepared

August 27, 2021

## C. Device Name

*Trade/Proprietary Name:* Discectomy Navigation Ready Instruments and Universal Navigation Adaptor Set

*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 Names

*Primary Predicate Device:*

SYMPHONY™ Navigation Ready Instruments and Universal Navigation Adaptor Set (K201661)

*Additional Predicate Devices:*

Synthes Navigable Pedicle Preparation Instruments (K122211)

Brainlab Spine & Trauma Navigation System (K212245)

## E. Device Description

Discectomy Navigation Ready Instruments:

The Discectomy Navigation Ready Instruments are reusable instruments used for disc space preparation, including discectomy or bony resection. These instruments are designed for navigated and non-navigated use. Navigation of these instruments is achieved using the DePuy Synthes Universal Navigation Adaptor Set (UNAS) and associated navigation arrays. For further details on UNAS, refer to the UNAS labeling.

The Discectomy Navigation Ready Instruments are part of the DePuy Synthes Navigation Ready Instruments Portfolio. The instruments include Cobb Elevators, Curettes and a Bone Graft Delivery Device.

Universal Navigation Adaptor Set:

The Universal Navigation Adaptor Set (UNAS) contains reusable spine surgical instruments used to aid in determining the correct location and trajectory of spinal instruments and implants. The UNAS has an interface between third-party navigation systems and the DePuy Synthes Navigation Ready Instruments. The UNAS can only be used with Brainlab and Medtronic StealthStation® navigation systems. The UNAS includes:

- Brainlab compatible UNAS Navigation Arrays,
- Brainlab compatible Navigation Rings and
- Medtronic compatible Navigation Ring ST.

The Navigation Rings and Navigation Ring ST mate with compatible DePuy Synthes Navigation Ready Instruments. These instruments include implant site preparation and implant insertion instruments as well as access and discectomy instruments.

When the Brainlab compatible Navigation Ring is attached to the Navigation Ready Instrument, a UNAS Navigation Array can be attached and the instrument can be used only with the Brainlab Navigation System as either a manually calibrated and/or pre-calibrated instrument.

When the Navigation Ring ST is attached to the Navigation Ready Instrument, a Medtronic SureTrak® II Universal Tracker Fighter array (SureTrak II array) can be attached, and the instrument can be manually calibrated only with the Medtronic StealthStation navigation system.

## F. Indications for Use

Discectomy Navigation Ready Instruments:

The Discectomy Navigation Ready Instruments when used with the compatible Universal Navigation Adaptor Set are intended to assist the surgeon in locating anatomical structures to facilitate disc space preparation, including discectomy or bony resection. These are indicated for use in surgical spinal procedures, in which:

- the use of stereotactic surgery may be appropriate, and
- 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 and associated navigation arrays.

These procedures include but are not limited to spinal fusion. The Discectomy Navigation Ready instruments can be pre-calibrated with the Brainlab Navigation System.

Universal Navigation Adaptor Set:

The Universal Navigation Adaptor Set (UNAS) is intended for use with the compatible DePuy Synthes Navigation Ready Instruments to assist the surgeon in locating anatomical structures in either open or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which:

- the use of stereotactic surgery may be appropriate, and
- 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 and associated tracking arrays.

These procedures include but are not limited to spinal fusion. The DePuy Synthes Navigation Ready Instrument, when used with UNAS, can be pre-calibrated and/or manually calibrated with the Brainlab Navigation System, where other navigation systems require manual calibration and tracking arrays supplied by the navigation system manufacturer.

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

The technological characteristics, including material, design and performance as well as intended use of the Discectomy Navigation Ready Instruments and the

Universal Navigation Adaptor Set are consistent with those of the predicate devices.

## H. Materials

The Discectomy Navigation Ready Instruments are manufactured from metals including Stainless Steels (420 SS, 17-4PH SS, 18-8 SS) with TiAlN (Titanium Aluminium Nitride) coating and Radel (polyphenylsulfone) or Silicone rubber for the handles.

## I. Performance Data

The performance data for the subject devices consists of the following evaluations:

- Accuracy Verification:
  - Fulfillment of navigation systems instrument accuracy requirements
  - Instrument Length Comparison to Predicate Device
  - Array Characteristics Comparison to Predicate Device
- Navigation Connection Repeatability for Pre-Calibrated Instruments
- CAD Model Evaluation
- Simulated Use Evaluation

## J. Conclusion

The indications for use of the Discectomy Navigation Ready Instruments and the Universal Navigation Adaptor Set are consistent with those of the predicate devices. The technological characteristics of the Discectomy Navigation Ready Instruments and the Universal Navigation Adaptor Set in terms of design, materials and performance are consistent with those of the predicate devices. The Discectomy Navigation Ready Instruments and the Universal Navigation Adaptor Set are substantially equivalent to the predicate devices.