April 16, 2025

Medyssey Co, Ltd.
℅ Christine Scifert
Partner
MRC Global
9085 East Mineral Circle
Suite 110
Centennial, Colorado 80112

Re: K242806
Trade/Device Name: Medyssey Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 17, 2024
Received: March 17, 2025

Dear Ms. Scifert:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242806

Device Name

Medyssey Navigation System

Indications for Use *(Describe)*

The Medyssey Navigation System is indicated for use during the preparation and placement of Medyssey screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Medyssey Navigation System is reusable and is specifically designed for use with the Medtronic Navigation StealthStation System which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where reference to a rigid anatomical structure such as a vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy. Use of the Medyssey Navigation System is limited to use only with ILIAD™ Spinal Fixation System and Zenius™ Spinal Fixation System (including Hedjet and ARTeMIS pedicle screw systems).

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.

510(k) Summary

Medyssey Navigation System
15 April 2025

Company: Medyssey Co, Ltd.
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Chungcheongbuk-do, Korea 27116
(484) 427-7060

Company Contact: Taehyun Park
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Official Correspondent: Christine Scifert – MRC Global, LLC
Christine.scifert@askmrcglobal.com
901-831-8053

Trade Name: Medyssey Navigation System

Common Name: Orthopedic Stereotaxic Instrument

Classification: Class II

Regulation Number: 21 CFR 882.4560 (Stereotaxic Instrument)

Panel: Orthopedic

Product Code: OLO

Device Description:
Medyssey Navigation System is comprised of reusable instruments intended to be used in conjunction with the Medtronic StealthStation® Navigation System and its associated NavLock arrays to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. The Medyssey Navigation System is comprised of Bone Taps and Screw Drivers. These instruments are made of medical grade stainless steel. The Medyssey Navigation System is supplied clean and non-sterile, to be sterilized by the end user.

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Substantial Equivalence:

The subject Medyssey Navigation System is substantially equivalent to the following predicate device:

Primary Predicate:

- Medtronic Navigation, Inc – NAVIGATED CD HORIZON SOLERA SCREWDRIVERS, TAPS, ILIAC TAPS, LEGACY TAPS (K124004)

Reference Devices:

- Medyssey ILIAD™ Spinal Fixation System (K181978)
- Medyssey Zenius Spinal Fixation System, including Hedjet™ Spinal Fixation System and ARTeMIS™ Percutaneous MIS Spinal Fixation (K232218)

Similar to the predicate navigated instruments, Medyssey Navigation System instruments are intended to be used with the Medtronic's StealthStation® System to assist the surgeon in locating anatomical structures. Additionally, the Medyssey Navigation System instruments and their predicate devices have similar technological characteristics, including design, dimensions, materials and technology, and they function in the same manner. Performance testing demonstrates that the Medyssey Navigation System instruments are substantially equivalent to the predicate devices. Thus, it can be concluded that the subject device does not raise new questions about safety and effectiveness.

Performance Testing:

A comparative dimensional analysis was conducted to verify that the Medyssey Navigation System instruments are appropriate for their intended use, to ensure functionality, accuracy and compatibility with the Medtronic StealthStation® System using the NavLock Tracker, and to demonstrate substantial equivalence to the predicate instruments. The reprocessing (cleaning and sterilization) validations were conducted per ANSI/AAMI ST98 and ISO 17665. Additionally, biocompatibility data was leveraged from K181978 and K232218.

Conclusion:

Based on the comparative dimensional analysis results, the subject device is determined to be substantially equivalent to the predicate device.