July 26, 2024

Medivis, Inc.
Amy Lynn
Chief Compliance Officer
920 Broadway
16th Floor
New York, New York 10010

Re: K233725
Trade/Device Name: Spine Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: November 15, 2023
Received: November 21, 2023

Dear Amy Lynn:

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.

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,

Tejen D. Soni -S

For
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.

510(k) Number *(if known)*
K233725

Device Name
Spine Navigation System

Indications for Use *(Describe)*
The Spine Navigation system is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures. Their use 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 the spine, can be identified relative to CT imagery of the anatomy.
This can include the spinal implant procedures, such as Posterior Pedicle Screw Placement in the sacro-lumbar region.
The headset of the Spine Navigation system displays 2D stereotaxic screens and a virtual anatomy screen. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient imagery. The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning.
The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

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

Contact Details

Applicant Name: Medivis, Inc.
Applicant Address: 920 Broadway, 16th Floor, New York, NY 10010 USA
Applicant Contact Telephone: +1 954-600-8299
Applicant Contact: Amy Lynn
Applicant Contact Email: amy@medivis.com

Device Name

Device Trade Name: Spine Navigation System
Common Name: Stereotaxic Instrument
Classification Name: Orthopedic Stereotaxic Instrument
Regulation Number: 882.4560
Product Code: OLO

Legally Marketed Predicate Devices

Predicate #: K190929
Predicate Trade Name: xvision spine system (XVS)
Product Code: OLO

Device Description Summary

The Medivis Spine Navigation System is an image-guided navigation system designed to assist surgeons in placing pedicle screws accurately during spinal surgery. The Medivis Spine Navigation System is comprised of software, a head-mounted display (HMD), passive reflective markers and reusable components. The device provides various image display options and manipulation features, primarily controlled through the touchscreen monitor. An HMD serves as an adjunct display and functions as an optical 3D tracking component for patient and surgical tool localization. The device registers patient data to the surgical environment through IR tracking.

Intended Use/Indications for Use

The Spine Navigation system is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures. Their use 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 the spine, can be identified relative to CT imagery of the anatomy. This can include the spinal implant procedures, such as Posterior Pedicle Screw Placement in the sacro-lumbar region.

The headset of the Spine Navigation system displays 2D stereotaxic screens and a virtual anatomy screen. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient imagery. The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning.

The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

Indications for Use Comparison

The Medivis Spine Navigation System subject device is substantially equivalent to the predicate device, Augmedics Ltd. xvision spine system (XVS) K190929. The Medivis subject device is substantially equivalent to the predicate because both devices have the same intended use and the subject device's minor technological differences do not raise different questions of safety and effectiveness compared to the predicate device.

Technological Comparison and Conclusion

The Medivis Spine Navigation System is similar in its technological features to its predicate device, the xvision Spine System (K190929). Both systems are intended as an aid for precisely locating anatomical structures in spine procedures. In addition, both systems consist of similar types of components and involve the same principles of operation. Both systems use a computer to host and run the navigation software and DICOM images. Both systems use optical cameras levering IR sensors to track the position of the surgical instruments in relation to the surgical anatomy. Both systems include a headset, which is positioned on the surgeon's head, and is designed to provide 2D and stereoscopic 3D augmented reality (AR) see-through display with overlaid navigation information, onto a patient's anatomy. The subject device the uses a see-through near eye display (Microsoft HoloLens 2) for displaying superimposed information of 2D images and 3D images from DICOM compliant medical imaging modalities onto patient's anatomy.