March 8, 2024

Comerge AG
% Frederike Bruhschwein-Mandic
Senior Consultant
Confinis Ag
Hauptrasse 16
Dudingen, 3186
Switzerland

Re: K230195
Trade/Device Name: Neo ADVISE software
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 4, 2024
Received: March 4, 2024

Dear Frederike Bruhschwein-Mandic:

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,

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.*

510(k) Number *(if known)*
K230195

Device Name
Neo ADVISE System

Indications for Use *(Describe)*
The Neo ADVISE™ System is indicated to calculate the relative positions and distances between implanted Neo Pedicle Screw System™ screws, as estimated by visually identifying screw guides, to estimate rod length, visualize rod positioning, and create a rod template that can be used to visually guide the manually creation a contoured rod by the surgeon, with a mechanical rod bender. The Neo ADVISE™ System can be used in posterior open or percutaneous spine surgery in the thoracic, lumbar, and/or sacral spine when using the Neo Pedicle Screw System™.

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 K230195

Neo ADVISE System

## I. SUBMITTER

Applicant Name: Comerge AG

Applicant Adress: Bubenbergstrasse 1 Zurich 8045

Switzerland Applicant Contact Telephone: +41445525264

Applicant Contact: Mr. Beat Hugi

Applicant Contact Email: beat.hugi@comerge.net

Correspondent Name: confinis ag

Correspondent Address: Hauptstrasse 16 Dudingen 3186

Switzerland Correspondent Contact Telephone: +4915201892430

Correspondent Contact: Mrs. Frederike Brühschwein-Mandic

Correspondent Contact Email: frederike.bruehschwein@confinis.com

Date prepared: March 07, 2024

## II. DEVICE

Device Trade Name: Neo ADIVSE system

Common Name: Stereotaxic instrument

Classification Name Orthopedic Stereotaxic Instrument

Regulation Number: 882.4560

Product Code: OLO

## III. PREDICATE DEVICE

Predicate #: K122742

Predicate Trade Name: NuVasive Bendini

Product Code: OLO

## IV. DEVICE DESCRIPTION

The Neo ADVISE system is a tool that supports the surgeon in open and percutaneous spinal surgeries performed with the Neo Medical Pedicle Screw System (K222256). After the placement of the pedicle screws, the software scans the the screw head positions and shows them in

Augmented Reality (AR) on an iPad. Based on the scanned screw positions, the software displays the distance between the screw heads and calculates the minimum rod length. The surgeon can select any of the pre-bent or straight rods of the Neo PSS and check the placement of the rod in the patient's body without touching the body or taking X-Ray images. The software calculates the distance between the screw head and the rod in the coronal and sagittal plane for the selected rod, indicating possible screw head adjustments.

Again, based on the scanned screw position, the software can generate a custom bent rod template that follows the path through all screw heads. This provides the surgeon with a rod template that assists the surgeon in rod bending. The rod template is displayed in a 1-1 scale on the device in the sagittal and coronal plane, allowing the surgeon to copy the rod shape according to the template.

The scanning of the screw heads can be performed using two distinct scanning methods, 3D scanning and Marker detection. 3D Scanning does not require any additional hardware. The surgeon scans each guide separately by overlaying the physical guide with a virtual guide in AR. 3D Scanning of the guides is limited to 10 guides. The Marker Detection scanning method allows the scanning of up to 20 guides. This is achieved by the use of the Neo Markers and the Neo Marker Base. The Neo Markers are attached to each guide, providing the software with a defined pattern, similar to QR codes, that can be recognized by the software.

The Neo ADVISE System consists of several components. The software runs on an Apple iPad, which is put into a sterile bag to allow use in the sterile environment of the patient's area. The Neo Markers and the Neo Marker Base are needed to allow the scanning of the guides using the Marker Detection scanning method.

## V. INDICATIONS FOR USE

The Neo ADVISE™ System is indicated to calculate the relative positions and distances between implanted Neo Pedicle Screw System™ screws, as estimated by visually identifying screw guides, to estimate rod length, visualize rod positioning, and create a rod template that can be used to visually guide the manually creation a contoured rod by the surgeon, with a mechanical rod bender. The Neo ADVISE™ System can be used in posterior open or percutaneous spine surgery in the thoracic, lumbar, and/or sacral spine when using the Neo Pedicle Screw System™.

## VI. INDICATIONS FOR USE COMPARISON

Both the Neo ADVISE System and the predicate Bendini Spinal Rod Bending System are used to locate the screw position during spinal surgery and relative to the identified positions, generate bend instructions to shape a spinal rod.
The Neo ADVISE System is intended to be used with off-the-shelf rod benders while the Bendini system has a dedicated rod bending instrument.
The Bendini system can be used with any pedicle screw system while the Neo ADVISE System is dedicated for use with the Neo Pedicle Screw System (K222256) only.

Like the NuVasive Bendini Spinal Rod Bending System the Neo ADVISE System is intra-operatively digitizing the relative location of anatomical landmarks (i.e. the position of the pedicle screws), through the use of a camera and markers that are pre-fixed on the screw guides (same as the pointer stylus with NuVasive Bendini).

The differences in the indications for use are not critical to the intended surgical use of the devices as in both cases, a final intra-operative X-ray must be taken to confirm the spinal rod placement at the end of the procedure.

## VII. TECHNOLOGICAL COMPARISON

Augmented reality and optical/electromagnetic localizer systems share similarities in their use during orthopedic surgery. The Neo ADVISE System´s software utilizes the augmented reality functionality of an Apple iPad to scan the position of guides and pedicle screws, without the need for traditional tracking arrays or pre-operative data planning. Instead, markers may be used to

enhance object recognition. The Apple iPad's camera and sensors provide the interface for communication between the user and the software.

Similarly, the predicate device cleared under K122742 also uses a localized pointer or stylus to intraoperatively digitize the relative location of anatomical landmarks, which are then interpreted by proprietary algorithms, in place of the stereotaxic principle.

## VIII. PERFORMANCE DATA

Non-clinical testing included two cadaver studies to evaluate the Neo ADVISE System, a usability study including a follow-up study to evaluate the human factors/usability aspects of the Neo ADVISE System, and bench testing.

The first cadaver study, conducted by 11 German orthopedic and trauma surgeons, utilized a biomechanical pilot study design with a single human cadaveric spine specimen. One investigator inserted 6 polyaxial pedicle screws (Neo Pedicle Screw SystemTM) percutaneously at levels L1-S1 on one side of the spine, resulting in instrumentation across 5 levels for fusion.

The second cadaver study aimed to assess the accuracy and effectiveness of the Neo ADVISE™ System in assembling and fixing posterior screw-rod constructions in thoraco-lumbo-sacral spine fusion surgery. Using CBCT (Cone-beam computed tomography systems) scans, primary endpoints measured translation of screw heads along sagittal and transverse axes, as well as angular change (Cobb angle) along sagittal and coronal planes. Four German spine surgeons conducted the study, demonstrating that AR-guided surgery maintained anatomy during rod placement and fixation.

The usability studies of the Neo ADVISE System's device-user interface, focused on identifying preventable errors attributable to device design or labeling and affirmed the usability of the Neo ADVISE™ system.

No clinical tests have been submitted.

## IX. CONCLUSION

Based on equivalence of indications for use, technology characteristics and operational principle the substantial equivalence between the new and the predicate device has been demonstrated. The Neo ADVISE System, is at least as safe and effective as the legally marketed predicate Nuvasive Bendini Spinal Rod Bending System.