October 9, 2020

Stryker Corporation
Maya Schiel
Staff Regulatory Affairs Specialist
Boetzinger Strasse 41
Freiburg, Baden-Wuerttemberg D-79111
Germany

Re: K202609
Trade/Device Name: Instrument Clamps Electromagnetic
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: September 3, 2020
Received: September 9, 2020

Dear Maya Schiel:

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,

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202609

Device Name
Instrument Clamps Electromagnetic

Indications for Use *(Describe)*
The Instrument Clamp Electromagnetic Sphere and Instrument Clamp Electromagnetic Universal are accessories to the Electromagnetic Navigation Unit and are intended for navigating conventional surgical instruments.

The Stryker ENT Navigation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT or MR based model of the anatomy.

Example procedures include, but are not limited to the following ENT procedures:
- Transphenoidal access procedures;
- Intranasal procedures;
- Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies;
- ENT related anterior skull based procedures.

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.

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510(k) Summary

Special 510(k): Instrument Clamps Electromagnetic

Submitter Information

510(k) Submitter	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 79111 Freiburg, Germany
FDA Establishment Number	8010177
Contact Person	Maya Schiel Staff Regulatory Affairs Specialist Phone: +49 30 311 911 89 Mail: maya.schiel@stryker.com
Date Submitted	September 3, 2020

Subject Device

Trade / Proprietary Name	Instrument Clamps Electromagnetic
Common Name	Ear, Nose, And Throat Stereotaxic Instrument
Classification	Class II
Classification Product Code	PGW
Classification Name	Stereotaxic Instrument
Classification Regulation	21 CFR 882.4560

Legally Marketed Predicate Device

Predicate Device Name	Scopis Extended Instrument Set EM Instrument Clamps Universal Tracker Electromagnetic
Predicate Device 510(k) Number	K171661

The Scopis Extended Instrument Set EM was cleared under K171661 by Scopis GmbH in September 2017. This submission was an extension to the previously cleared Scopis Hybrid Navigation System (K161491).

Scopis GmbH was acquired by Stryker in November 2017. In July 2018, the legal manufacturer for the devices was changed to Stryker Leibinger GmbH & Co. KG. Since October 2019, the devices have also been also physically manufactured in Freiburg under the Stryker Leibinger Quality Management System. The 510(k) ownership was also transferred from Scopis GmbH.

As part of the post-acquisition integration the Scopis name of the system was changed from *Scopis Hybrid Navigation System* to *Stryker ENT Navigation System.*

The cleared instrument set contains instrument clamps and an electromagnetic tracker, which needs to be mounted on top of a clamp to enable tracking of conventional surgical instruments. Since the *Instrument Clamps Electromagnetic* are a combination of these devices, they are viewed as variants of the predicate device. The *Instrument Clamps Electromagnetic* themselves have the same intended purpose and indications and are therefore considered line extensions.

Device Description

The *Instrument Clamps Electromagnetic* are part of the *Stryker ENT Navigation System*. The basic principle of this system is the generation of an electromagnetic (EM) field with an EM-emitter (Field Generator). The EM devices have sensor coils that transform the detected EM field into an analogue signal. This signal is transmitted via cable to the *Electromagnetic Navigation Unit*. The signal is then evaluated, and the tracking data is transmitted to the platform. This technology allows tracking instruments without a line-of-sight requirement.

The *Instrument Clamps Electromagnetic* are to be used for localizing surgical instruments in a dedicated working volume. They are intended to be mounted on suitable surgical rigid instruments. The body of the clamp incorporates the required sensor coils, which enables tracking of conventional instruments. For accurate navigation, the instrument with the attached electromagnetic clamp needs to be calibrated prior to use.

Two electromagnetic clamps are in scope of this submission:

- *Instrument Clamp Electromagnetic Sphere*: Clamping interface optimized for tracking instruments with a circular cross-section between 2.0 mm and 4.6 mm in diameter (inclusive)
- *Instrument Clamp Electromagnetic Universal*: Clamping interface optimized for tracking instruments with angular cross-section (e.g. forceps) between 3.0 mm and 6.0 mm in diameter (inclusive)

The subject devices are not intended to have patient contact. Their bodies are made of PEEK and the clamps and screws are manufactured from titanium.

They are reusable devices that need to be reprocessed prior to first use. They are limited to 10 uses.

Intended Use and Indications

The *Instrument Clamp Electromagnetic Sphere* and *Instrument Clamp Electromagnetic Universal* are accessories to the *Electromagnetic Navigation Unit* and are intended for navigating conventional surgical instruments.

The *Stryker ENT Navigation System* is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT or MR based model of the anatomy.

Example procedures include, but are not limited to the following ENT procedures:

- Transsphenoidal access procedures;
- Intranasal procedures;
- Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies;
- ENT related anterior skull-based procedures.

Comparison of Technological Characteristics

This submission is about the modification of combining two products (clamp and electromagnetic tracker) into one (electromagnetic clamp).

The combination was achieved by integrating the electromagnetic sensor coil into the body of the clamp, as opposed to an EM tracker unit that must be separately attached, resulting in a smaller and lighter device. The one-piece electromagnetic clamp requires one step less of preparation and post-processing in the OR, since the devices do not need to be assembled or disassembled.

The *Instrument Clamps Electromagnetic* are attached to conventional surgical instruments the same way as the predicate clamps. The step of attaching a separate electromagnetic tracker (as in predicate) is not required, as it is already incorporated into the subject device.

The subject and predicate devices are **identical** in the following characteristics:

- 510(k) holder
- FDA product codes and regulation
- Intended Use
- Indications for Use
- Application Area
- Type of Use
- Type of Patient Contact
- Tracking Technology
- Usage
- Material
- Packaging
- Fixation
- Calibration
- Compatibility

The subject and predicate devices **differ** in the following ways:

The key requirements of the *Instruments Clamps Electromagnetic* are to be smaller and lighter, but with the same functionalities as the variants of the predicate. This requires a design that allows the device to be both clamp and tracker in one device. Therefore, the same type of electromagnetic sensor coil used in the predicate is directly incorporated into the body of the subject device in a more compact form.

Performance Data

Non-Clinical Testing

A risk analysis was completed for subject devices in compliance with ISO 14971 to identify required verification and validation activities in order to evaluate the impact of the device modification and to mitigate potential risks. This submission includes appropriate supporting data to show the safety and effectiveness of the *Instrument Clamps Electromagnetic*.

The following bench testing was performed to evaluate performance (accuracy), reprocessing, and electrical safety.

Table 1: Performance Data

Scientific discipline	Test summary
Performance - Accuracy	To ensure accuracy, subject devices are tested in accordance with ASTM F2554. The devices meet state-of-the-art acceptance criteria for point accuracy, precision and distance accuracy.
Reprocessing	Subject devices are reusable instruments and were therefore validated in compliance with the respective FDA guidance for reprocessing medical devices including respective TIRs. The steam sterilization was also conducted in compliance with ISO 17665-1 and ANSI/AAMI ST79. The respective instructions follow ISO 17664.
Electrical Safety	The devices are used as parts of the *Stryker ENT Navigation System,* which is defined as ME Equipment. Therefore, devices were checked and certified for compliance with ANSI/AAMI ES 60601-1 as accessories to a ME Equipment.

All cited standards are FDA-recognized consensus standards

Clinical Testing

No clinical testing was deemed necessary for this 510(k) submission.

Conclusion

The intended use and fundamental scientific technologies of subject devices and their predicate are identical. The subject devices are line extensions to the variants of the predicate and are therefore part of the same ENT Navigation System, following the same operating principles and conditions. The change of combining two devices into one does not affect the indications for use, tracking technology, calibration or other basic features. The device modifications do not raise different questions of safety and effectiveness than the predicate device.

Risk management was conducted in accordance with ISO 14971 and does not show any unacceptable risk or new risks when compared to the predicate. Verification testing demonstrates that the subject devices are at least as safe and effective as the predicate.

In conclusion, the information provided demonstrates that the *Instrument Clamps Electromagnetic* are at least as safe and effective as their predicate (K171661) and do not introduce different questions of safety or effectiveness., and therefore supports a determination of substantial equivalence.