July 12, 2022

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

Re: K221098
Trade/Device Name: Scopis ENT Software, Scopis ENT Software with TGS, Scopis Planning Software, Electromagnetic Navigation Unit
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: April 12, 2022
Received: April 14, 2022

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 Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221098

Device Name
Stryker ENT Navigation System
with Scopis® ENT Software, Scopis® ENT Software with TGS®, Scopis® Planning Software and Electromagnetic Navigation Unit

Indications for Use *(Describe)*
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.

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

Traditional 510(k): Scopis ENT Software

510(k) Number: K221098

Submitter Information

510(k) Submitter	Stryker Leibinger GmbH & Co. KG Boetzinger Strasse 41 79111 Freiburg, Germany
FDA Establishment Number	8010177
Contact Person	Maya Schiel Senior Staff Regulatory Affairs Specialist Phone: +49 30 311 911 89 Mail: maya.schiel@stryker.com
Date Submitted	April 12, 2022

Subject Device

Trade / Proprietary Name	Scopis ® ENT Software Scopis ® ENT Software with TGS ® Scopis ® Planning Software Electromagnetic Navigation Unit
Common Name	Ear, Nose, And Throat Stereotaxic Instrument
Classification	Class II, 21 CFR 882.4560
Classification Product Code	PGW
Classification Name	Stereotaxic Instrument

Legally Marketed Predicate Device

Predicate Device Name and 510(k) Number	TGS Guidewire and updated Scopis ENT Software (K193118) - Scopis ENT Software - Scopis ENT Software with TGS Scopis Hybrid Navigation System EM (K161491) - Electromagnetic Navigation Unit

The purpose of this Traditional 510(k) Submission is to gain clearance for the new version of the Scopis software variants and the updated *Electromagnetic Navigation Unit* as parts of the *Stryker ENT Navigation System*.

The initial clearance of this navigation system was achieved via K161491 in 2017 by Scopis GmbH. 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 physically manufactured in Freiburg under the Stryker Leibinger Quality Management System. The 510(k) ownership was also transferred.

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 Scopis software applications were most recently cleared under K193118 in 2020. The computer platform called *Electromagnetic Navigation Unit* was cleared within the first submission for the system with K161491.

Device Description

The *Stryker ENT Navigation System* is a computer-assisted image-guided surgery system. The system displays the position of navigated instruments on a model of the patient's anatomy based on preoperative images (CT or MRI) using electromagnetic tracking technology. The position of the instruments and the patient are localized within an electromagnetic field produced by a field generator. The navigation of instruments relative to the patient's anatomy is established via registration of the patient's anatomy to the preoperative images via anatomical landmarks, or surface matching. The position of navigated instruments is then displayed with respect to preoperative images.

The system comprises a computer platform, the software, patient trackers, pointers and suction tubes, instrument trackers, and a dedicated calibration body.

This submission is about the new version 3.6 of the Scopis software application, and the updated computer platform called *Electromagnetic Navigation Unit* with the new operating system version 3.6.A.

Electromagnetic Navigation Unit

The *Electromagnetic Navigation Unit* serves as platform of the *Stryker ENT Navigation System*. This is the computer platform where the navigation software is installed on, and where the main components required for navigation are connected to, like *Field Generator* or electromagnetic instruments.

Optionally, the *Electromagnetic Navigation Unit* allows to display the output of external endoscopic imaging devices from Stryker or other manufacturers. Instrument trackers allow for navigation of corresponding endoscope optics. A dedicated calibration body is utilized to calibrate endoscopes and enable *Augmented Reality* overlay of endoscopic video images.

Scopis Software Application

The software application provides the functionality necessary to import the patient image data sets, build the image-based model of the anatomy, plan a surgical procedure, and display location of navigated instruments relative to the model of the anatomy.

There are two navigation software variants: *Scopis ENT Software* and *Scopis ENT Software with TGS*. In comparison to *Scopis ENT Software, Scopis ENT Software with TGS* offers the ability to create more advanced surgical plans such as target paths to anatomy and display these during navigation. Both Scopis navigations software variants are installed on the *Electromagnetic Navigation Unit*.

In addition, there will be one designated planning software called *Scopis Planning Software*. This variant offers identical functionality for creation of advanced surgical plans like *Scopis ENT Software with TGS* but does not include any navigation functionality. This software is intended to be used on a planning system, like a personal computer of the surgeon, to prepare the application of one of the navigation software variants. Accordingly, after planning the data are to be transferred to the *Electromagnetic Navigation Unit* for surgical navigation with one of the navigation software variants.

Intended Use

The *Scopis ENT Software* is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures together with the *Stryker ENT Navigation System*. The software application is indicated for any medical condition in which the use of computer-assisted surgery may be appropriate

The *Scopis ENT Software with TGS* is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures together with the *Stryker ENT Navigation System.* The software application is indicated for any medical condition in which the use of computer-assisted planning and surgery may be appropriate.

The *Scopis Planning Software* is intended as an aid for precisely locating anatomical structures in preparation for either open or percutaneous procedures together with the *Stryker ENT Navigation System*. The software application is indicated for any medical condition in which the use of computer-assisted pre-operative planning may be appropriate.

The *Electromagnetic Navigation Unit* is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures.

Indications for Use

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 new version of the Scopis software application and the updated operating system running on the corresponding computer platform.

The general way the devices are used, and function has not been changed. So, the subject and predicate devices are **identical** in most characteristics, such as:

- FDA product codes and regulation
- Intended users and target patient population
- Indications for Use
- Application Area
- Type of Use and type of Patient Contact
- Intended Environment
- Tracking Technology
- Programming Language
- Operating Principles
- Modes of Operation
- Image Import
- Reference Images
- Patient Registration
- Planning Objects
- Control Mechanism

The new software version has been developed to add some new features to the software. These **new features** include, but are not limited to:

- Support tracking multiple instruments of the same kind
- Improved guidance during patient registration
- Field generator alignment support
- Introducing a new software variant, the *Scopis Planning Software*
- Cybersecurity improvements

Further, the operating system running on the computer platform of the navigation system called *Electromagnetic Navigation Unit* has been updated to *Windows 10 IoT Enterprise LTSC 2019.*

Performance Data

Non-Clinical Testing

Non-clinical design verification and validation activities were conducted to provide evidence that the subject devices successfully meet their requirements and perform according to their specifications and intended uses. Table 2 provides a summary of the performance data

Table 2: Summary of Performance Data

Test Item	Test summary
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.
Software	Scopis software applications were subject to verification and validation testing in compliance with IEC 62304 and FDA guidances. All testing criteria were met.
Electrical Safety and Electromagnetic Compatibility	Applicable devices in scope were checked and certified for compliance with ANSI/AAMI ES 60601-1 and IEC 60601-1-2.
Safety	Verification of risk controls specified in the corresponding risk analysis is in accordance with ISO 14971.
Security	Verification of the security of the operating system with respect to technical requirements (NIST 800-53 and FDA Guidances) and operating system updates. All testing criteria were met.

Clinical Testing

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

Conclusion

The subject devices have the same main functionalities and follow the same operating principles as their predicates. The fundamental technological characteristics do not change. The only differences are caused by the introduction of additional features of the new software version and some improvements, e.g., for cybersecurity. The performance data demonstrate that the subject devices meet their specifications and the requirements on safety and effectiveness.

In conclusion, the information provided demonstrates that the *Electromagnetic Navigation Unit* and the three software variants are at least as safe and effective as their predicates (K161491, K193118) and do not raise different issues of safety or effectiveness., and therefore supports a determination of substantial equivalence.