February 21, 2020

Stryker ENT
Bruce Backlund
Principal Regulatory Affairs Specialist
3600 Holly Lane North, Suite 40
Plymouth, Minnesota 55447

Re: K193118
Trade/Device Name: TGS Guidewire and updated Scopis Software
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: PGW
Dated: January 24, 2020
Received: January 24, 2020

Dear Bruce Backlund:

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 Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193118

Device Name
TGS Guidewire

Indications for Use *(Describe)*

The TGS Guidewire 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:

- Transsphenoidal access procedures
- Intranasal procedures
- Sinus procedures, such as maxillary antrostomies, ethmoidectomies, sphenoidotomies/sphenoid explorations, turbinate resections, and frontal sinusotomies
- ENT-related anterior skull base 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

Date Prepared: February 20, 2019

Submitter Information:
Stryker ENT
3600 Holly Lane North, Suite 40
Plymouth, MN 55447

Establishment Registration: 3006345872

Contact Information:
Bruce Backlund
Principal Regulatory Affairs Specialist
(763) 762-5902
bruce.backlund@stryker.com

Device Information:

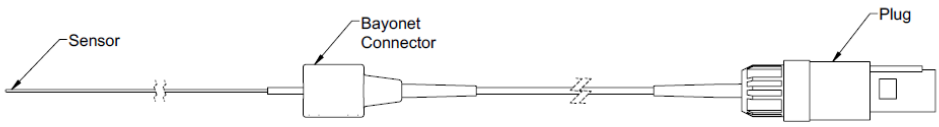
Trade Name: TGS Guidewire
Common Name: Stereotaxic Instrument
Classification: Class II, 21 CFR 882.4560
Device: Ear, Nose, and Throat Stereotaxic Instrument
Product Code: PGW

Predicate Devices:

Predicate Device	Manufacturer	510(k) No.
Guidewire 0.6 Single Use	Fiagon GmbH	K161940
Scopis Extended Instrument Set EM	Scopis GmbH	K171661
Stryker ENT Navigation System EM	Scopis GmbH	K161491

Device Description:

The TGS Guidewire is a single use, sterile, disposable instrument intended to be used with the Stryker ENT Navigation System and the XprESS LoProfile ENT Dilation System. The instrument is an electromagnetically navigated device which consists of a sensor in a protective sheath that can be inserted into the working lumen of the XprESS device, a bayonet connector to secure the device to the XprESS luer and a cable and plug to connect the device to the navigation system. The navigation system displays the position of the instrument in the preoperative scans.



TGS Guidewire

The Scopis ENT software options include:

Name	Catalog Number	Surgical Planning Capability
Scopis ENT Software	8000-020-001	Without surgical planning capability
Scopis ENT Software with TGS	8000-020-002	With surgical planning capability

Intended Use:
The TGS Guidewire is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. It is intended for use with the Stryker ENT Navigation System and the XprESS LoProfile ENT Dilation System during balloon sinus dilation procedures.

The Scopis ENT Software is an accessory to the Electromagnetic Navigation Unit and intended for controlling of the hardware of the navigation unit.

The Scopis ENT Software with TGS (Target Guided Surgery) is an accessory to the Electro-magnetic Navigation Unit and intended for controlling of the hardware of the navigation unit.

Indications for Use:
The TGS Guidewire 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:

- Transsphenoidal access procedures
- Intranasal procedures
- Sinus procedures, such as maxillary antrostomies, ethmoidectomies, sphenoidotomies/sphenoid explorations, turbinate resections, and frontal sinusotomies
- ENT-related anterior skull base procedures

Contraindications:
The instrument must not be exposed to MRI or used in a Magnetic Resonance Environment. The MRI exposure might magnetize the sensor.

Technological Characteristics and Substantial Equivalence:
The TGS Guidewire (subject device) has the same indications for use and fundamental scientific technology as the predicate device Guidewire 0.6 Single Use [K161940].

The subject device TGS Guidewire has the same technological characteristics (i.e., principal of operation, basic design, functionality, materials, biocompatibility, packaging, and sterilization) as the predicate device Guidewire 0.6 Single Use [K161940]. The subject guidewire and predicate guidewire are both single-use, sterile, pre-calibrated flexible guidewires with a sensor at the instrument tip, and both are compatible with the Stryker XprESS LoProfile device.

The Scopis ENT Software and Scopis ENT Software with TGS (subject device) has the same indications for use and fundamental scientific technology as the predicate devices Scopis Extended Instrument Set EM [K171661] and Scopis Hybrid Navigation System EM [K161491].

The subject Scopis ENT Software and Scopis ENT Software with TGS has the same technological characteristics (i.e., algorithm, architecture, planning functionalities, patient

registration, tracking method, position accuracy, and cyber security) as the predicate devices Scopis Extended Instrument Set EM [K171661] and Scopis Hybrid Navigation System EM [K161491]. The only difference is that the subject software user interface was updated to add a new icon to indicate the TGS Guidewire is the active instrument.

The TGS Guidewire and updated Scopis ENT Software have the same indications for use and fundamental scientific technology as the predicate devices [K161940, K171661, K161491]. The TGS Guidewire and updated Scopis ENT Software is substantially equivalent to the predicate devices.

Performance Data:
Performance testing for the TGS Guidewire included biocompatibility, design verification (dimensional, functional, strength, HFE/UE verification testing), packaging, shelf life and design validation (HFE/UE). Performance testing showed that the device meets design specifications and performs as intended.

Navigation accuracy was performed through bench testing in order to establish the substantial equivalence to the predicate devices. Testing was also completed to ensure functionality and compatibility with the ENT Navigation System.

The measured navigation accuracy using the TGS Guidewire is 0.75 ± 0.27mm compared to the Fiagon predicate device K161940 with a bench accuracy 1.27 ± 0.4mm.

Conclusion:
In conclusion, the TGS Guidewire and updated Scopis ENT Software indications for use and technological characteristics are the same as or equivalent to those of one or more of the predicate devices. The differences between the subject device and the predicate devices (e.g., update of user interface to add a new icon indicating the TGS Guidewire being the active instrument) do not raise different questions of safety or effectiveness and performance testing has been conducted to demonstrate the subject device performance is substantially equivalent to the predicate devices.