February 14, 2020

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

Re: K193502
Trade/Device Name: TGS Universal Headrest with Mounting Arm
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: December 17, 2019
Received: December 18, 2019

Dear Denise Thompson:

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 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)*

Device Name

TGS Universal Headrest with Mounting Arm

Indications for Use *(Describe)*

The Stryker ENT Navigation System, of which the TGS Universal Headrest with Mounting Arm is an accessory, 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 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 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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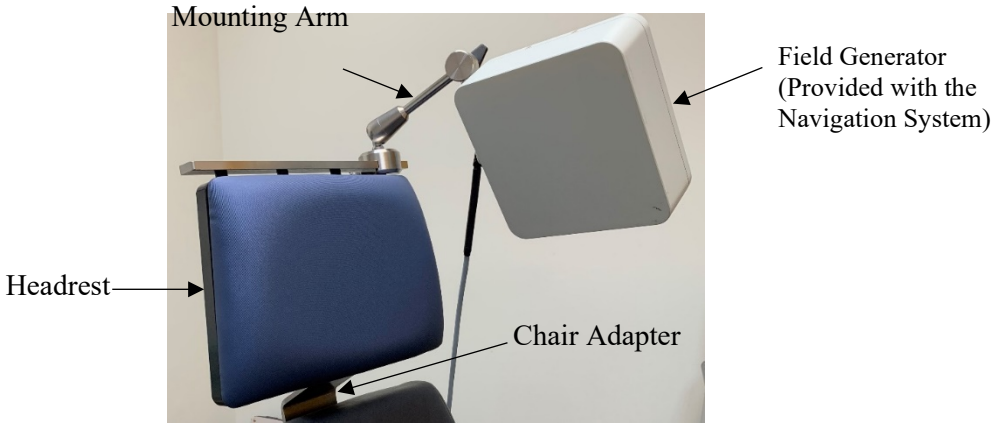
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Date Prepared:	December 17th, 2019
Submitter Information:	Stryker ENT 3600 Holly Lane North, Suite 40 Plymouth, MN 55447
Establishment Registration:	3006345872
Contact Information:	Denise Thompson Principal Regulatory Affairs Specialist (269) 888-0219 denise.thompson@stryker.com
Device Information:	
Trade Name:	TGS Universal Headrest with Mounting Arm
Common Name:	Image Guided Surgery System
Classification Name:	Ear, Nose, and Throat Stereotaxic Instrument
Product Code:	PGW
Classification:	Class II
Regulation Number:	21 CFR 882.4560
Predicate Devices:	Navigation Headrest Office, K133573 Field Generator Mounting Arm, K161491

Device Description:

The TGS Universal Headrest with Mounting Arm is a reusable device intended to be used with the Stryker ENT Navigation System. It consists of three main components: a headrest, mounting arm and chair adapters. The mounting arm provides fixation for the field generator of the navigation system allowing it to be positioned in proximity to the patient creating an optimal electromagnetic field. The headrest provides support for the patient's head while undergoing navigation guided procedures. The chair adapters are fixed to the headrest to allow the headrest to be connected to various ENT procedure chairs



TGS Universal Headrest with Mounting Arm

Intended Use:
The TGS Universal Headrest with Mounting Arm is an accessory to the Stryker ENT Navigation System and intended for positioning the Field Generator. It also provides a resting surface for the patient to place their head during procedures requiring navigation.

Indication for Use:
The Stryker ENT Navigation System, of which the TGS Universal Headrest with Mounting Arm is an accessory, 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 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 base procedures.

Contraindications:
None

Technological Characteristics:
The technological characteristics of the TGS Universal Headrest and Mounting Arm are very similar to the predicate devices, the Navigation Headrest Office (an accessory to the Fiagon Navigation System, K133573) and the Field Generator Mounting Arm (an accessory to the Stryker ENT Navigation System, K161491).

The TGS Universal Headrest and Mounting Arm and its predicates all:

- position the field generator of a navigation system,
- have articulating hinged design features,
- achieve different positions through use of locking mechanisms,
- are for use by healthcare professionals only (physicians), and
- are provided non-sterile and intended to be cleaned and disinfected between uses.

Substantial Equivalence:
The TGS Universal Headrest with Mounting Arm has been shown to be substantially equivalent to the predicate devices, the Navigation Headrest Office and the Field Generator Mounting Arm based on Intended Use, Indications for Use, Principles of Operation and technological characteristics.

The TGS Universal Headrest with Mounting Arm most closely resembles the primary predicate, the Navigation Headrest Office. The main difference between devices relates to the design of the mounting mechanism (arm versus bracket) for the field generator. The subject device's mounting mechanism more closely resembles the mounting mechanism of the secondary predicate, the Field Generator Mounting Arm.

While there are some minor design differences between the subject and predicate devices, these differences do not raise different questions of safety or efficacy.

Performance Data:
Bench testing was performed to demonstrate that the TGS Universal Headrest with Mounting Arm performs as intended and meets the design specifications. The testing included dimensional, functional, simulated use, compatibility and distribution testing. Design validation involved ENT physicians familiar with image guided sinus surgery and was conducted to demonstrate that the intended users could perform the critical tasks related to use of the TGS Universal Headrest with Mounting Arm in its expected use environment.

Conclusion:
The TGS Universal Headrest with Mounting Arm has been shown to be substantially equivalent to the predicate devices based on Intended Use, Indications for Use, Principles of Operation and technological characteristics. The minor design differences between the subject and predicate devices do not raise different questions of safety or efficacy and bench performance testing has been conducted to demonstrate the TGS Universal Headrest with Mounting Arm performs as intended and equivalently to the predicate devices.