July 10, 2020

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

Re: Q200834
Trade/Device Name: TGS Universal Headrest with Mounting Arm
Evaluation of Accessory Classification Under Section 513(f)(6) - Accessory Classification Request
Regulation Number: 21 CFR 882.4565
Regulation Name: Field Generator Positioning Device
Regulatory Classification: Class I
Product Code: QLV
Dated: April 15, 2020
Received: April 17, 2020

Dear Ms. Thompson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Accessory Classification Request for classification of the TGS Universal Headrest with Mounting Arm, a prescription device under 21 CFR 801.109 that is intended for positioning the field generator of an electromagnetic based stereotaxic navigation system and for providing a resting surface for the patient to place their head during procedures requiring navigation.

FDA concludes that this device should be classified into Class I. This order, therefore, classifies the TGS Universal Headrest with Mounting Arm, and substantially equivalent devices of this generic type, into Class I under the generic name Field Generator Positioning Device.

FDA identifies this generic type of device as:

> **Field Generator Positioning Device**. A field generator positioning device is a manual, mechanical device intended to position the field generator of an electromagnetic based stereotaxic navigation system in proximity to a patient. The device may operate independently or adapt existing medical equipment, such as a procedure chair or surgical bed, by using a mechanical interface.

Section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) was added by section 707 of the FDA Reauthorization Act of 2017 (FDARA) on August 18, 2017 and was effective on October 17, 2017 (Pub. L. 115-52). This provision establishes a pathway for manufacturers or importers to request classification of accessories distinct from another device upon written request. The classification is based

upon the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request proper classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days announcing the classification.

Alternatively, under section 513(f)(6)(C), a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days announcing the classification.

FDA received your Accessory Classification request on April 17, 2020 to classify the TGS Universal Headrest with Mounting Arm into Class I under section 513(f)(6)(D)(ii) of the FD&C Act. In order to classify the TGS Universal Headrest with Mounting Arm into Class I or II, the proposed class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the Accessory Classification request, FDA has determined that the TGS Universal Headrest with Mounting Arm intended for positioning the field generator of an electromagnetic based stereotaxic navigation system and for providing a resting surface for the patient to place their head during procedures requiring navigation, can be classified in Class I. FDA has determined that Class I (general controls) provide reasonable assurance of the safety and effectiveness of the device type.

The Field Generator Positioning Device is subject to the general controls of the FD&C Act. Section 510(l) of the FD&C Act (21 U.S.C. 360(l)) provides that a Class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does not meet these criteria and, therefore, premarket notification is not required for the device. Thus, persons who intend to market this device need not submit a premarket notification containing information on the Field Generator Positioning Device they intend to market prior to marketing the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Please be advised that FDA's decision to grant this Accessory Classification request does not mean that FDA has determined that your device complies with other requirements of the FD&C Act or any Federal statutes or regulations administered by other Federal agencies. You must comply with all applicable requirements under the FD&C Act, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and, if applicable, 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order is on file in the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and is available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may market your device as described in the Accessory Classification request, provided that your device complies with the general control provisions of the FD&C Act.

If you have any questions concerning this classification order, please contact Payton Lin at 240-402-6580 or Payton.Lin@fda.hhs.gov.

Sincerely,

/s/

Malvina B. 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