May 13, 2022

Thompson Surgical Instruments Inc.
Tiffany Bush
Regulatory Engineer
10341 E Cherry Bend Road
Traverse, Michigan 49684

Re: K210615
Trade/Device Name: Thompson Brain Retractor Table Mounted (TM), Thompson Brain Retractor Skull Clamp Mounted (SCM)
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-Retaining Retractor For Neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: April 11, 2022
Received: April 12, 2022

Dear Tiffany Bush:

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,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K210615

Device Name
Thompson Brain Retractor Skull Clamp Mounted
Thompson Brain Retractor Table Mounted

Indications for Use *(Describe)*
The Thompson Brain Retractor Table Mounted and Skull Clamp Mounted Systems are indicated for self-retaining retraction of soft tissue during neurological procedures to provide surgical access and exposure. The Thompson Brain Retractor Systems also allow attachment for applicable accessories and function as a hand-rest for the surgeon.

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
K210615

Submitter Name:	Thompson Surgical Instruments, Inc.
Submitter Address:	10341 E Cherry Bend Rd Traverse City, MI 49684
Contact Person:	Tiffany Bush, Regulatory Engineer
Phone Number: **Fax:** **Email:**	231-303-1854 231-922-0174 tiffany.bush@thompsonsurgical.com
Date Prepared:	May 10, 2022
Device Trade Name:	Thompson Brain Retractor Table Mounted (TM), Thompson Brain Retractor Skull Clamp Mounted (SCM)
Classification Name:	Self-retaining retractor for neurosurgery
Device Class:	Class II
Classification Regulation:	21 CFR 882.4800
Product Code:	GZT
Predicate Device:	Greenberg Retractor and Handrest (pre-amendment device)
Reference Devices:	Phantom Fukushima Neurological Holding Systems, Phantom Mastability Neurological Holding Systems (K161318) Budde-Halo Retractor (K830332)
Indications for Use:	The Thompson Brain Retractor Table Mounted and Skull Clamp Mounted Systems are indicated for self-retaining retraction of soft tissue during neurological procedures to provide surgical access and exposure. The Thompson Brain Retractor Systems also allow attachment for applicable accessories and function as a hand-rest for the surgeon.
Device Description:	Thompson Surgical Instruments Brain Retractor is a reusable manual instrument made from stainless steel and aluminum, as indicated. It is composed of materials that can be reused with steam sterilization methods. It is provided to the customer non-sterile. The Thompson Brain Retractor is a retractor system used to create

adequate exposure of the cranial region to assist surgeons in accessing areas for surgery. The system is comprised of a stainless-steel frame with 1/2-inch diameter frame components, which create a plane over the access point in the skull of the patient. The system uses stainless steel flexible arms that are attached to the frame to hold blades (stainless steel), which ultimately retract the tissue for the needed exposure. The frame also acts as a rest for the surgeons' wrists/hands during the procedure, as well as an attachment point for various accessories to aid the surgeon (ex: pattie tray).
The system uses clamps, cam actuation, and screws to construct and support the frame. The flexible arms are attached to the frame via screw down mechanism and the flexible arms are tightened into a semi-rigid state also using a screw mechanism, very similar to the function of all the predicate devices.

Technological and Performance Characteristics:

The Thompson Brain Retractor was found to be similar to the predicate. Three fundamental similarities are:

1. Basic design: Both the Thompson Brain Retractor and the predicate device consist of stainless-steel frames for surrounding the cranial region with flexible arms and blades that retract tissue during surgery. General size, shape, weight, and materials are not identical but are very similar.

2. Sterilization and Biocompatibility: Both the Thompson Brain Retractor and predicate device are designed for repeat use and can be reprocessed with cleaning and steam sterilization.

3. Use: Both the Thompson Brain Retractor and predicate device are manipulated using common mechanisms to lock and unlock the components from one another. The devices are to be used in a healthcare facility by a trained health care personnel or medical professional such as a surgeon, PA circulating nurse, surgical tech, etc.

Primary differences are related to minor differences in size, shape, and overall look. However, performance data demonstrates that the differences do not raise new questions of safety and effectiveness. Please see further comparison below.

Comparison to Predicate Device: **Table 5.1:** Predicate and Reference Device Comparison

Description	**Thompson Brain Retractor System**	**K161318 TeDan Fukushima** *Reference Device*	**Pre-amendment Codman Greenberg** (sold by Symmetry. Mediflex, Integra) **Predicate Device**	**K830332 Budde-Halo** *Reference Device*
Indications for Use	The Thompson Brain Retractor Table Mounted and Skull Clamp Mounted Systems are indicated for self-retaining retraction of soft tissue during neurological procedures to provide surgical access and exposure. The Thompson Brain Retractor Systems also allow attachment for applicable accessories and function as a hand-rest for the surgeon.	Similar	Similar	Similar
Intended Use	The Thompson Retractor is intended for use during surgical procedures in order to provide surgical access and exposure.	Same	Same	Same
Product Code	GZT	Same	Same	Same
Target Population	Intended for surgeon use on individuals, adult or pediatric, during surgery	Same	Same	Same
Anatomical Site	Cranial Region	Same	Same	Same
Where Used	Hospital, health facility	Same	Same	Same
Human Factors	Highly trained surgeon or other health professional intended user with general knowledge of similar types of device	Same	Same	Same
Design	Mitigation of use related hazards	-	-	-
Material	Stainless Steel and Anodized Aluminum	Stainless Steel, Anodized Aluminum, Polymer	Stainless Steel	Stainless Steel, Composite Carbon Fiber, Titanium Arms

Description	**Thompson Brain Retractor System**	**K161318 TeDan Fukushima** *Reference Device*	**Pre-Amendment Codman Greenberg** (sold by Symmetry. Mediflex, Integra)	**K830332 Budde-Halo** *Reference Device*
Sizes	Various blade sizes, and various frame component sizes, lengths, and configurations	Same	Same	Same
Frame	Table Mounted and Skull Clamp Mounted	Table Mounted and Skull Clamp Mounted	Skull Clamp Mounted, can be Table Mounted	Skull Clamp Mounted, can be Table Mounted
Frame	Circular or Curved	Curved Arms	Straight Arms	Circular
Flex Arm Length	9”	14.5”, 16.5” and 6.5”	9.5”	9”, optional 6” and 12”
Blades	Flat Malleable Tapered Blades: Length: 9” Widths: 1/4” x 3/4” 5/32” x 5/8” 1/8” x 1/2” 3/32” x 3/8” 1/16”x 1/4” Straight Malleable Blades with 1/8” rod attachment: 6mm x 102mm 9mm x 102mm 16mm x 102mm 19mm x 102mm 25mm x 102mm	Similar	Same	Similar, click-in mechanism blades
Classification	21 CFR 882.4800	Same	Same	Same
Device Description	The Thompson Brain Retractor is a retractor system used to create adequate exposure of the cranial region to assist surgeons in accessing areas for surgery. The system is comprised of a stainless-steel frame with 1/2-inch diameter frame components, which create a plane over the access point in the skull of	Similar, knobs and pattie tray are anodized aluminum, instrument holder is polymer	Similar, Uses straight frame components	Similar, also comes in a radiolucent version. Frame components are not 1/2-inch diameter

Description	**Thompson Brain Retractor System**	**K161318 TeDan Fukushima** *Reference Device*	**Pre-Amendment Codman Greenberg** (sold by Symmetry. Mediflex, Integra)	**K830332 Budde-Halo** *Reference Device*
	the patient. The system uses stainless steel flexible arms that are attached to the frame to hold blades (stainless steel), which ultimately retract the tissue for the needed exposure. The frame also acts as a rest for the surgeons' wrists/hands during the procedure, as well as an attachment point for various accessories to aid the surgeon (ex: pattie tray).			
Compatibility with other devices	SCM – Compatible with most skull clamps, test attachment with skull clamp before use. TM – Compatible with operating room table.	Similar	Compatible with many Skull Clamps or may attach to the side rails of the operating room table.	Compatible with MAYFIELD Skull Clamps, has separate side rail supports to facilitate use without skull clamp.
Sterility	Non-Sterile, no single use components	Non-Sterile, has some single-use components	Non-Sterile	Non-Sterile

Non-Clinical Performance Studies:

A brief discussion of tests used to support the conclusion of substantial equivalence with the predicate device is provided below.

Test	Test Method Summary	Result
Sterilization	The Thompson Brain Retractor and predicate device are provided non-sterile and can be cleaned and reprocessed with similar guidelines. The Thompson Brain Retractor can be reprocessed following the Thompson Brain Retractor IFU (brifu) through comparative analysis of the design features with previously validated components. The Thompson Brain Retractor contains no single-use components.	Device met acceptance criteria in the comparative analysis for achieving a minimum sterility assurance level (SAL) of 10^{-6} when compared to similar previously validated components.
Biocompatibility	The blade components of the Thompson Brain Retractor Systems are intended to come into direct contact with human tissue during use and were evaluated and tested per the requirements of ISO 10993-1 and the recommendations of the FDA Guidance, "Use of ISO-10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process." The battery of testing included the following endpoint tests:	Device met the acceptance criteria for al tests. Passing results in all endpoint testing demonstrates the patient contacting devices are biocompatible and meet the standard requirements for ISO 10993-1.
	Cytotoxicity (MEM Elution)	Pass – Non-cytotoxic
	Sensitization (Guinea Pig Maximization Test)	Pass – Non-sensitizer
	Irritation (Intracutaneous Reactivity)	Pass – Non-irritant
	Acute Systemic Toxicity	Pass
	Material Mediated Pyrogenicity	Pass
	Hemolysis (Indirect)	Pass
Mechanical	Various strength and life cycle testing was performed on components of the Brain Retractor Systems in comparison to the predicate device. The tests specified below were to compare strength and life cycle of key components the subject device with those of the predicate. The mechanical testing specified for key components included:	Devices passed all testing per the acceptance criteria and performed as well as the predicate device.
	Blades – Life cycle bend comparison to predicate	Pass – met acceptance criteria performed as well as the predicate.
	Flexible Arm Holder – Life cycle of screw-down mechanism	Pass – met acceptance criteria with no new questions of safety and effectiveness.

	Flexible Arm Holder – Flex Arm Strength and comparison to predicate failure mode	Pass – met acceptance criteria and performed as well as the predicate.
	Flexible Arm Holder – Life cycle of blade attachment mechanism	Pass – met acceptance criteria with no new questions of safety and effectiveness.
	Frame Components – Strength of assembled frame	Pass – met acceptance criteria with no new questions of safety and effectiveness.
	Skull Clamp Mount – Screw-down strength comparison to predicate	Pass – met acceptance criteria and performed as well as the predicate.
	Skull Clamp Mount – Cycle testing of half inch rod connection	Pass – met acceptance criteria with no new questions of safety and effectiveness.
Functional	Validation with a neurosurgeon in a simulated clinical environment covering the clinical workflow with the subject devices and a comparison predicate device was conducted to assure no new issues of safety or effectiveness were raised.	Device met acceptance criteria and performed as well as the comparison predicate device.

Clinical Performance Studies: This premarket notification report does not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion: The Thompson Brain Retractor Table Mounted and Thompson Brain Retractor Skull Clamp Mounted are substantially equivalent to the Greenberg Retractor and Handrest (pre-amendment device). The differences between the Thompson Brain Retractor and the predicate do not change the intended use or raise new questions of safety and effectiveness.