DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 30, 2016

Medtronic Navigation, Inc.
Christopher Perman
Principal Regulatory Affairs Specialist
826 Coal Creek Circle
Louisville, Colorado 80027

Re: K162604
Trade/Device Name: Cranial Reducing Tubes
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: December 8, 2016
Received: December 9, 2016

Dear Mr. Perman:

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. 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); 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162604

Device Name
Cranial Reducing Tubes

Indications for Use *(Describe)*
The Cranial Reducing Tubes are intended to maintain the position of instruments or devices placed using stereotactic guidance during planning and operation of neurological procedures performed in conjunction with the use of the Medtronic StealthStation System Image Guided Workstation. The devices were not tested for MR compatibility, and are not intended for use in an MRI environment.

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

I. SUBMITTER

Medtronic Navigation, Inc.
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USA

Telephone: 720-890-3200
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Contact Person: Christopher Perman
Date Prepared: September 16, 2016

II. DEVICE

Name of Device: Cranial Reducing Tubes
Common Name: Stereotaxic Instrument
Classification Name: Stereotaxic Instrument (21 CFR 882.4560)
Regulatory Class: Class II (21 CFR 882.4560)
Product Code: HAW

III. PREDICATE DEVICE

Navigus Trajectory Guide, K992304 (Medtronic Neuromodulation)
Navigus II Trajectory Guide, K012366 (Medtronic Neuromodulation)

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Medtronic Cranial Reducing Tubes (CRT) are metallic, reusable accessories that maintain the position of instruments or devices placed using stereotactic guidance during neurosurgical procedures. The CRTs have differing inner diameters (4.0 mm, 3.2 mm, and 1.7mm). The CRT inserts into the Precision Aiming Device accessory of the Medtronic StealthStation System. This is conducted in an operating room environment where navigational trajectories are determined by the StealthStation System using preoperative MR/CT scans of the patient.

V. INDICATIONS FOR USE

The Cranial Reducing Tubes are intended to maintain the position of instruments or devices placed using stereotactic guidance during planning and operation of neurological procedures performed in conjunction with the use of the Medtronic StealthStation System Image Guided Workstation. The devices were not tested for MR compatibility, and are not intended for use in an MRI environment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device Name	Cranial Reducing Tubes (Subject Device)	Navigus II Trajectory Guide (Predicate Device)	Navigus Manual Trajectory Guide (Predicate Device)
510k Number	K162604	K012366	K992304
Indications for Use	The Cranial Reducing Tubes are intended to maintain the position of instruments or devices placed using stereotactic guidance during planning and operation of neurological procedures performed in conjunction with the use of the Medtronic StealthStation System Image Guided Workstation. The devices were not tested for MR compatibility, and are not intended for use in an MRI environment.	The Navigus II Trajectory Guide is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI/CT environment and in conjunction with the use of an Image Guided Workstation System using preoperative MR and/or CT imaging. These procedures include biopsies, catheter and electrode introduction. The device is ETO sterilized and for one time use.	The Trajectory Guide is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures within the MRI/CT environment and in conjunction with MR/CT-imaging. The Trajectory Guide is intended as an integral part of procedures that have traditionally used stereotactic methodology. These procedures include biopsies, catheter and electrode introduction. The device will provide accurate delivery of devices or instruments to target sites 3mm and larger.
Sterility	Provided non-sterile Steam Sterilization Reusable	Provided sterile ETO Sterilization Single Use	Provided sterile ETO Sterilization Single Use
Number of Lumens	1	5	1
Lumen Diameter	1.7mm, 3.2mm, 4.0mm	2.2mm	1mm, 2mm, 3mm, 5mm
MR Compatibility	No	Yes	Yes
Patient-Contacting Material	Stainless Steel	SABIC Valox™ Resin	Polycarbonate
Guide for instruments and devices	Yes	Yes	Yes
Trajectory aligned by Image Guided Workstations (IGW)	Yes	Yes	No
Able to interface stereotactic navigation tool for guidance	Yes, optical tracking	Yes, optical tracking	No
Navigational Performance	Mean Error ≤2.00 mm and ≤2.00º	Value not available	Delivery of devices or instruments to target sites ≥3mm

For comparison of the technological characteristics between the subject and predicate devices, the attribute of navigational performance for the subject device value was presented as mean navigational error and the predicate device presented as a minimum target size. Although these values cannot be directly compared, the safety and efficacy for navigational accuracy of the subject device was demonstrated in bench testing.

VII. PERFORMANCE DATA

Testing was completed to ensure the functionality and compatibility with the identified Medtronic navigation systems and instruments. The following table summarizes the performance testing completed:

Test	Results	Conclusions
System Accuracy	The CRTs when used with compatible accessories and the StealthStation system have demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees.	The CRTs are accurate for their intended use.
Useful Life	The CRTs maintain acceptable use when exposed to cleaning, sterilization, and use conditions over the useful life of the device.	The CRTs meet the intended use throughout the useful life of the device.
Repeated Drilling Exposure	The CRTs maintain acceptable use and are functional when repeatedly drilled through over the useful life of the device.	The CRTs meet the intended use when repeated drilled through over the useful life of the device.
Usability	The CRTs satisfy the user's needs and product usability.	The instruments can be used correctly by the defined users.
Biocompatibility		
Cytotoxicity – MEM Elution ISO 10993-5	Cell culture treated with test sample exhibited no reactivity (Grade 0)	Non-cytotoxic
Maximization Sensitization – ISO 10993-10	Intradermal injection of representative material test sample showed no evidence of sensitization.	Non-sensitizer
Intracutaneous Irritation-ISO 10993-10	Intracutaneous injection of representative material test sample showed no evidence of irritation.	Non-irritant
Acute Systemic Toxicity–ISO 10993-11	Systemic injection of representative material test sample showed no mortality or toxicity.	Non-toxic

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the Cranial Reducing Tubes should perform as intended in the specified use conditions. The non-clinical data demonstrate that the Cranial Reducing Tubes perform comparably to the predicate device that is currently marketed for the same intended use.