DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 25, 2015

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

Re: K141833
Trade/Device Name: Stylet, 23cm, Skull-Mount Patient Tracker, Non-Invasive Patient Tracker, Tracer Pointer, Touch-n-Go Pointer, Navigation Pointer
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: February 20, 2015
Received: February 23, 2015

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,

Carlos L. Pena -S

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)*
K141833

Device Name
Non-Invasive Patient Tracker

Indications for Use *(Describe)*
The Non-Invasive Patient Tracker is indicated for use as a stereotactic reference frame to track the position of patient anatomy during navigated cranial and ENT procedures in adult and pediatric patients. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial and ENT software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141833

Device Name
Skull-Mount Patient Tracker

Indications for Use *(Describe)*
The Skull-Mount Patient Tracker is indicated for use as a stereotactic reference frame to track the position of patient anatomy during navigated cranial and ENT procedures. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial and ENT software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

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)

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# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141833

Device Name
Stylet, 23 cm

Indications for Use *(Describe)*
The Stylet is indicated for use in precisely locating anatomical structures during navigated cranial procedures. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

The Stylet is indicated for use in the following procedures:
- General ventricular catheter placement
- Pediatric ventricular catheter placement
- Tumor resections
- Skull base procedures
- Craniotomies/craniectomies
- Transsphenoidal 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)

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# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141833

Device Name
Tracer Pointer

Indications for Use *(Describe)*
The Tracer® Pointer is indicated for use in registering patient anatomy and in precisely locating anatomical structures during navigated cranial procedures in adult and pediatric patients. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

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)

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# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141833

Device Name
Touch-n-Go Pointer

Indications for Use *(Describe)*
The Touch-n-Go Pointer is indicated for use in registering patient anatomy during navigated cranial procedures in adult and pediatric patients. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

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)

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# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141833

Device Name
Navigation Pointer

Indications for Use *(Describe)*
The Navigation Pointer is indicated for use in precisely locating anatomical structures during navigated cranial procedures. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

The Navigation Pointer is indicated for use in the following procedures:
- General tumor resections
- Pediatric tumor resections
- Skull base procedures
- Craniotomies/craniectomies
- Transsphenoidal 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)

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**510(k) Summary**

## I. SUBMITTER

Medtronic Navigation, Inc.
826 Coal Creek Circle
Louisville, Colorado 80027
USA

Telephone: 720-890-3200
Fax: 720-890-3500

Contact Person: Christopher Perman
Date Prepared: March 24, 2015

## II. DEVICE

**Name of Device:** Stylet, 23cm, Tracer® Pointer, Touch-n-Go Pointer, Navigation Pointer, Skull-Mount Patient Tracker, Non-Invasive Patient Tracker
**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

StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option, K001284
Catheter Introducer for the StealthStation® System, K022126
StealthStation® System Update, K050438

No reference devices were used in this submission.

## IV. DEVICE DESCRIPTION

The AxiEM™ Instruments (Stylet, 23cm, Tracer® Pointer, Touch-n-Go Pointer, Navigation Pointer) and Trackers (Skull-Mount Patient Tracker, Non-Invasive Patient Tracker) are single-use, sterile devices compatible with AxiEM™-enabled Medtronic computer assisted surgery systems. The instruments and trackers are electromagnetically navigated devices used for the purpose of localizing patient anatomy, patient registration, and tracking patient location during stereotactic surgery procedures.

Each device incorporates a tracking system within the instrument or tracker. The mobile emitter of the navigation system generates a low-energy magnetic field that is detected by the tracking system within the device. The navigation system software displays the location of the instrument's tip within multiple patient image planes and other anatomical renderings.

## V. INDICATIONS FOR USE

Stylet, 23cm
The Stylet is indicated for use in precisely locating anatomical structures during navigated cranial procedures. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

The Stylet is indicated for use in the following procedures:

- General ventricular catheter placement
- Pediatric ventricular catheter placement
- Tumor resections
- Skull base procedures
- Craniotomies/craniectomies
- Transsphenoidal procedures

Tracer® Pointer
The Tracer® Pointer is indicated for use in registering patient anatomy and in precisely locating anatomical structures during navigated cranial procedures in adult and pediatric patients. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

Touch-n-Go Pointer
The Touch-n-Go Pointer is indicated for use in registering patient anatomy during navigated cranial procedures in adult and pediatric patients. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

Navigation Pointer

The Navigation Pointer is indicated for use in precisely locating anatomical structures during navigated cranial procedures. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

The Navigation Pointer is indicated for use in the following procedures:

- General tumor resections
- Pediatric tumor resections
- Skull base procedures
- Craniotomies/craniectomies
- Transsphenoidal procedures

Skull-Mount Patient Tracker

The Skull-Mount Patient Tracker is indicated for use as a stereotactic reference frame to track the position of patient anatomy during navigated cranial and ENT procedures. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial and ENT software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

Non-Invasive Patient Tracker

The Non-Invasive Patient Tracker is indicated for use as a stereotactic reference frame to track the position of patient anatomy during navigated cranial and ENT procedures in adult and pediatric patients. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial and ENT software.

The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

### Stylet, 23cm

| Item | Subject Device<br>(Stylet, 23cm) | Predicate Devices |
|---|---|---|
| Indications for Use | The Stylet is indicated for use in precisely locating anatomical structures during navigated cranial procedures. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.<br><br>The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.<br><br>The Stylet is indicated for use in the following procedures:<br>• General ventricular catheter placement<br>• Pediatric ventricular catheter placement<br>• Tumor resections<br>• Skull base procedures<br>• Craniotomies/craniectomies<br>• Transsphenoidal procedures | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.<br>Example procedures include, but are not limited to:<br>Cranial Procedures:<br>Cranial biopsies<br>Tumor resections<br>Craniotomies/Craniectomies<br>Skull base procedures<br>Thalamotomies/Pallidotomies<br>ENT Procedures:<br>Transphenoidal procedures<br><br>***Catheter Introducer for the StealthStation® System (K022126)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.<br>Example procedures include, but are not limited to:<br>Cranial Procedures:<br>Cranial Biopsies<br>Placement<br>Tumor Resections |

| | | |
|---|---|---|
| | | Craniotomies/ Craniectomies<br>Skull Base procedures<br>Thalamotomies/Pallidotomies<br>Pituitary Tumor Removal<br>CSF Leak Repair<br>Pediatric Catheter Shunt Placement<br>General Catheter Shunt Placement<br><br>ENT Procedures:<br>Transphenoidal Procedures<br><br>***StealthStation® System Update (K050438)***<br><br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.<br>For the optical-based and EM-based system, example procedures include, but are not limited to:<br>Cranial Procedures:<br>Cranial Biopsies<br>Tumor Resections<br>Craniotomies/ Craniectomies<br>Skull Base procedures<br>Thalamotomies/Pallidotomies<br>Pituitary Tumor Removal<br>CSF Leak Repair<br>Pediatric Catheter Shunt Placement<br>General Catheter Shunt Placement<br><br>ENT Procedures:<br>Transphenoidal Procedures |

| | | |
|---|---|---|
| Establishment of Stereotactic Coordinates (Tracking Method) | Electromagnetic | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>Electromagnetic<br>***Catheter Introducer for the StealthStation® System (K022126)***<br>Electromagnetic or Optical<br>***StealthStation® System Update (K050438)***<br>Electromagnetic or Optical |
| System Accuracy | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. |
| Materials | -302 Spring Steel<br>-PET<br>-Loctite Adhesive | ***Catheter Introducer for the StealthStation® System (K022126)***<br>-302 Spring Steel<br>-PET<br>-Loctite Adhesive |
| Sterility | ETO Sterile/ Single Use | ***Catheter Introducer for the StealthStation® System (K022126)***<br>ETO Sterile/ Single Use |

## Tracer Pointer

| Item | Subject Device<br>(Tracer Pointer) | Predicate Devices |
|---|---|---|
| Indications for Use | The Tracer® Pointer is indicated for use in registering patient anatomy and in precisely locating anatomical structures during navigated cranial procedures in adult and pediatric patients. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.<br><br>The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.<br>***StealthStation® System Update (K050438)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. |
| Establishment of Stereotactic Coordinates (Tracking Method) | Electromagnetic | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>Electromagnetic<br>***StealthStation® System Update (K050438)***<br>Electromagnetic or Optical |
| System Accuracy | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. |
| Materials | -303 Stainless Steel<br>-Lustran 348 (ABS Plastic) | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>-Medical Grade SS<br>-Titanium<br>-Plastic |

| | | |
|---|---|---|
| Sterility | ETO Sterile/ Single Use | ***StealthStation® System Update (K050438)***<br>ETO Sterile/ Single Use |

## Touch-n-Go Pointer

| Item | Subject Device (Touch-n-Go Pointer) | Predicate Devices |
|---|---|---|
| Indications for Use | The Touch-n-Go Pointer is indicated for use in registering patient anatomy during navigated cranial procedures in adult and pediatric patients. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.<br><br>The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.<br>***StealthStation® System Update (K050438)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. |
| Establishment of Stereotactic Coordinates (Tracking Method) | Electromagnetic | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>Electromagnetic<br>***StealthStation® System Update (K050438)***<br>Electromagnetic or Optical |
| System Accuracy | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. |

| | | |
|---|---|---|
| Materials | -303 Stainless Steel<br>-Lustran 348 (ABS Plastic) | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>-Medical Grade SS<br>-Titanium<br>-Plastic |
| Sterility | ETO Sterile/ Single Use | ***StealthStation® System Update (K050438)***<br>ETO Sterile/ Single Use |

## Navigation Pointer

| Item | Subject Device (Navigation Pointer) | Predicate Devices |
|---|---|---|
| Indications for Use | The Navigation Pointer is indicated for use in precisely locating anatomical structures during navigated cranial procedures. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial software.<br><br>The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.<br><br>The Navigation Pointer is indicated for use in the following procedures:<br>• General tumor resections | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.<br>Example procedures include, but are not limited to:<br>Cranial Procedures:<br>Cranial biopsies<br>Tumor resections<br>Craniotomies/Craniectomies<br>Skull base procedures<br>Thalamotomies/Pallidotomies<br>ENT Procedures:<br>Transphenoidal procedures<br><br>***StealthStation® System Update (K050438)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long |

| | | |
|---|---|---|
| | • Pediatric tumor resections<br>• Skull base procedures<br>• Craniotomies/craniectomies<br>• Transsphenoidal procedures | bone, or vertebra, can be identified relative to a CT based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy.<br>For the optical-based and EM-based system, example procedures include, but are not limited to:<br>Cranial Procedures:<br>Cranial Biopsies<br>Tumor Resections<br>Craniotomies/ Craniectomies<br>Skull Base procedures<br>Thalamotomies/Pallidotomies<br>Pituitary Tumor Removal<br>CSF Leak Repair<br>Pediatric Catheter Shunt Placement<br>General Catheter Shunt Placement<br>ENT Procedures:<br>Transphenoidal Procedures |
| Establishment of Stereotactic Coordinates (Tracking Method) | Electromagnetic | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>Electromagnetic<br>***StealthStation® System Update (K050438)***<br>Electromagnetic or Optical |
| System Accuracy | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. |
| Materials | -304 Stainless Steel<br>-Lustran 348 (ABS Plastic) | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>-Medical Grade SS<br>-Titanium<br>-Plastic |
| Sterility | ETO Sterile/ Single Use | ***StealthStation® System Update (K050438)***<br>ETO Sterile/ Single Use |

## Skull-Mount Patient Tracker

| Item | Subject Device<br>(Skull-Mount Patient Tracker) | Predicate Devices |
|---|---|---|
| Indications for Use | The Skull-Mount Patient Tracker is indicated for use as a stereotactic reference frame to track the position of patient anatomy during navigated cranial and ENT procedures. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial and ENT software.<br><br>The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR based model or fluoroscopy images of the anatomy.<br>***StealthStation® System Update (K050438)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. |
| Establishment of Stereotactic Coordinates (Tracking Method) | Electromagnetic | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>Electromagnetic<br>***StealthStation® System Update (K050438)***<br>Electromagnetic or Optical |
| System Accuracy | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. |
| Materials | --Lustran 348 (ABS Plastic)<br>-Silicon 70<br>-Titanium Alloy Bone Screw | ***StealthStation® GoldenEye™ Micro-Magnetic Tracking System Option (K001284)***<br>-Medical Grade SS<br>-Plastic |
| Sterility | ETO Sterile/ Single Use | ***StealthStation® System Update (K050438)***<br>ETO Sterile/ Single Use |

## Non-Invasive Patient Tracker

| Item | Subject Device<br>(Non-Invasive Patient Tracker) | Predicate Devices |
|---|---|---|
| Indications for Use | The Non-Invasive Patient Tracker is indicated for use as a stereotactic reference frame to track the position of patient anatomy during navigated cranial and ENT procedures in adult and pediatric patients. It is indicated for use with Medtronic computer-assisted surgery systems using electromagnetic navigation and cranial and ENT software.<br><br>The Medtronic computer assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT-based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. | ***StealthStation® System Update (K050438)***<br>The StealthStation® System is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT based or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. |
| Establishment of Stereotactic Coordinates (Tracking Method) | Electromagnetic | ***StealthStation® System Update (K050438)***<br>Electromagnetic or Optical |
| System Accuracy | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. |
| Materials | -Pellethane 2363<br>-3M 9917 Medical Tape<br>-Santoprene<br>-3M 9916 Tape<br>-Loctite Epoxy | ***StealthStation® System Update (K050438)***<br>-3M 9874 Adhesive<br>-ABS Plastic |
| Sterility | ETO Sterile/ Single Use | ***StealthStation® System Update (K050438)***<br>ETO Sterile/ Single Use |

## VII. PERFORMANCE DATA

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

| Test | Results | Conclusions |
|---|---|---|
| System Accuracy | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. | Instruments are accurate for their intended use. Testing included predicate testing to demonstrate comparability. |
| Simulated Environment Accuracy | The system has demonstrated accuracy with a mean positional error of <2mm and mean trajectory error of <2 degrees. | Instruments are accurate for their intended use in the use environment |
| Skin Shift Test | Shifting of the NIPT during use is minimal and similar to existing methods of securing patient trackers for navigation. | Instrument performs as designed for its intended use. |
| Chemical Resistance | Adhesion of the NIPT to the patient is maintained when exposed to common chemical solutions present in the surgical environment. | Instrument performs as designed for its intended use. |
| Electrical Safety | The instruments conform to IEC 60601-1 and IEC 60601-1-2, electrical safety and EMC standards. | Instruments meet electrical safety and EMC requirements. |
| Shipping | The instruments and packaging are functional and intact after simulated shipping conditions. | The instruments in the designed package can be safely shipped. |
| General Requirements and Performance | The instruments tested demonstrate conformance with identified design and performance specifications. | The instruments perform as designed for their intended use. |
| MRI Compatibility | The patient trackers were demonstrated to be MR Conditionally-Safe in 1.5T and 3T MRI scanners. | The patient trackers can be used safely with MR scanners under the labeled conditions. |
| Usability | The instruments satisfy the user's needs and product usability. | The instruments can be used correctly by the defined users. |
| Accelerated Life Functionality | The instruments maintained functionality after exposure to accelerated life exposures and user conditions. | The instruments can be effectively used for their labeled shelf life. |
| Tool Cards | The instrument tools package has met the required interface needs of the application software. | The NIPT can be correctly selected as an instrument using the application software. |
| **Biocompatibility** | | |
| Cytotoxicity – MEM Elution | Cell culture treated with test sample exhibited no reactivity (Grade 0) | Non-cytotoxic |
| Maximization Sensitization – ISO 10993-10 | Intradermal injection of test sample showed no evidence of sensitization. | Non-sensitizer |
| Intracutaneous Irritation - ISO 10993-10 | Intracutaneous injection of test sample showed no evidence of irritation. | Non-irritant |
| Acute Systemic Toxicity–ISO 10993-11 | Systemic injection of test sample showed no mortality or toxicity. | Non-toxic |
| Pyrogenicity – USP | Intravenous injection of test sample showed no evidence of pyrogenicity. | Non-pyrogenic |

## VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the Stylet, 23cm, Tracer® Pointer, Touch-n-Go Pointer, Navigation Pointer, Skull-Mount Patient Tracker, Non-Invasive Patient Tracker devices should perform as intended in the specified use conditions. The non-clinical data demonstrate that the Stylet, 23cm, Tracer® Pointer, Touch-n-Go Pointer, Navigation Pointer, Skull-Mount Patient Tracker, Non-Invasive Patient Tracker devices perform comparably to the predicate device that is currently marketed for the same intended use.