April 17, 2023

Localite GmbH
Arno Schmitgen
Managing director
Auguststr. 1
Bonn, 53229
Germany

Re: K223577
Trade/Device Name: Localite TMS Navigator TS
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: March 16, 2023
Received: March 16, 2023

Dear Arno Schmitgen:

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,

Pamela D. Scott -S

Pamela D. Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine 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)*
K223577

Device Name
Localite TMS Navigator TS

Indications for Use *(Describe)*
The TMS Navigator TS helps users to plan, implement and document treatment involving TMS of the brain.

The system provides planning and navigation functions using anatomical MR data.

Regions of the brain to be stimulated can be determined on the basis of anatomy, functional areas or by entering previously calculated coordinates from brain atlases.

The product is intended for use with the MagVenture therapy systems supplied by Tonica Elektronik A/S (Farum, Denmark), more precisely the R20 and R30 stimulators, the R30 TMS stimulator with MagOption, the X100 stimulator and the X100 stimulator with MagOption only with following magnetic coils: C-100, C-B60, Cool-B65, Cool-B70, Cool D-B80, MC-125, MC-B70, MCF-75, MCF-125, MCF-B65 and MMC-140-II.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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) #: K223577

# 510(k) Summary

Prepared on: 2023-04-18

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Localite GmbH |
| Applicant Address | Auguststr. 1 Bonn 53229 Germany |
| Applicant Contact Telephone | 004922841012220 |
| Applicant Contact | Mr. Arno Schmitgen |
| Applicant Contact Email | quality@localite.de |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Localite TMS Navigator TS |
| Common Name | Stereotaxic instrument |
| Classification Name | Neurological Stereotaxic Instrument |
| Regulation Number | 882.4560 |
| Product Code | HAW |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K191422 | The Neural Navigator | HAW |
| K171902 | Nexstim Navigated Brain Therapy (NBT) System 2 | HAW |

## Device Description Summary

21 CFR 807.92(a)(4)

The TMS Navigator TS is a navigation system specifically designed to support transcranial magnetic stimulation (TMS).

It uses position data of the patient's head and the TMS coil acquired by an optical tracking system for display and navigation. The real-time display of the position of the TMS coil in the displayed MR data set provides visual support for navigation. With the help of the software, one or more locations for the TMS treatment can be planned as well as stimulated locations can be recorded, located in the used data set and thus documented.

These functionalities support the following use case:

Planning, execution and documentation of a TMS stimulation in the human brain.

Transcranial magnetic stimulation (TMS) uses so-called TMS coils to generate alternating electromagnetic fields to target brain areas. The depth of penetration, extent and nature of this effect (inhibitory or exhibitory) is influenced by the type of coil used, the strength and shape of the magnetic field and the repetition frequency used.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The TMS Navigator TS helps users to plan, implement and document treatment involving TMS of the brain.

The system provides planning and navigation functions using anatomical MR data.

Regions of the brain to be stimulated can be determined on the basis of anatomy, functional areas or by entering previously calculated coordinates from brain atlases.

The product is intended for use with the MagVenture therapy systems supplied by Tonica Elektronik A/S (Farum, Denmark), more precisely the R20 and R30 stimulators, the R30 TMS stimulator with MagOption, the X100 stimulator and the X100 stimulator with MagOption only with following magnetic coils: C-100, C-B60, Cool-B65, Cool-B70, Cool D-B80, MC-125, MC-B70, MCF-75, MCF-125, MCF-B65 and MMC-140-II.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use of the proposed device is as follows:

The TMS Navigator TS helps users to plan, implement and document treatment involving TMS of the brain.

The system provides planning and navigation functions using anatomical MR data.

Regions of the brain to be stimulated can be determined on the basis of anatomy, functional areas or by entering previously calculated coordinates from brain atlases.

The product is intended for use with the MagVenture therapy systems supplied by Tonica Elektronik A/S (Farum, Denmark), more precisely the R20 and R30 stimulators, the R30 TMS stimulator with MagOption, the X100 stimulator and the X100 stimulator with MagOption only with following magnetic coils: C-100, C-B60, Cool-B65, Cool-B70, Cool D-B80, MC-125, MC-B70, MCF-75, MCF-125, MCF-B65 and MMC-140-II.

The primary predicate (K191422) is "indicated for accurate positioning of the treatment coil [...] with respect to target brain regions based on data obtained from MRI measurements" according to its intended use. The reference predicate (K171902) provides similar intentions as the proposed device and can thus be seen as substantially similar.

The primary predicate (K191422) mentioned refer to the proprosed reference predicate (K171902). For the reference device (K171902) the intended use is summed up as follows: Nexstim Navigated Brain Therapy (NBT) System 2 is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

Comparing the intended use statements the following rationale reasons the difference:

The reference device comes as a complete system including a Transcranial Magnetic Stimulator (product code OBP), evoked response measurement and Electromyograph (product codes GWF, IKN) besides the navigation system for transcranial magnetic stimulation (product code HAW). Referring to the device description of the reference predicate the explanation is as follows: The Nexstim NBT System 2 consists of a group of devices designed to localize the stimulation site in the brain and deliver rTMS stimulation using controlling and interpretive software. Operational control of the Nexstim NBT System 2 is provided by the software. The Nexstim NBT System 2 combines magnetic resonance imaging based (MRI-based), three-dimensional (3-D) localization of cortical motor areas of the brain with non-invasive TMS and simultaneous electromyography (EMG) measurement to locate areas of the brain that are capable of evoking muscle responses when stimulated, and to locate the target area for depression therapy.

The proposed device covers the application of the localization of the brain area to be stimulated with MagVenture Therapy Systems from Tonica Elektronik (Farum, Denmark). For the localization of the treatment spot 3D MRI data is used to determine and locate targets for brain stimulation. During treatment the proposed navigation system helps to apply TMS on the previously determined target region.

In conclusion the proposed device including its application, safety and effectiveness is as well comparable to the reference predicate as a product subset.

## Technological Comparison

21 CFR 807.92(a)(6)

In comparison to the two legally marketed predicate and reference devices (K191422 and K171902) the subject device can be seen as substancially equivalent. The subject device does not include a TMS stimulator while it is intended to be used as an accessory for such as the predicate device (K191422). The intended use of the predicate device (K191422) is comparibly similar as both devices, the subject device as well as the predicate device (K191422), support TMS coil placement by MRI guidance to identify and locate brain regions to be stimulated. A comparison of the intended use of the reference predicate (K171902) needs to be complemented with a detail look into the device descriptions. There the TMS application is combined with "magnetic resonance imagingbased (MRI-based), three-dimensional (3-D) localization of cortical motor areas of the brain [...] and to locate the target area for depression therapy" which is similar to the intended use of the subject device.

The table below shows and overview over different technological characteristics, key components and features and furthermore provide general details about the devices as an overview. In summary the proposed device can be seen as substantially equivalent to its predicate device (K191422) and reference device (K171902).

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Summary nonclinical tests
The TMS Navigator TS was tested for performance in accordance with the following FDA Guidance Document:

Guidance for Industry and Food and Drug Administration Staff: Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions (December 2019)

A complete test report in accordance with the referenced FDA Guidance Document is provided in the attachments:

Test Report Bench Performance Test: Study measuring the system accuracy of typical navigated TMS sessions with the TMS Navigator TS using a measurement phantom and a TMS coil test probe in a simulated use environment demonstrating substantially equivalent results compared to comparable navigated TMS systems on the market

Conclusion
In total, 288 coordinate comparisons were deduced from eight test locations across 36 navigated TMS sessions. The sessions were performed with the TMS Navigator TS using a measurement phantom and a TMS coil test probe in a simulated use environment and varying hardware setups including all steps used in a real use scenario. On average, a system accuracy of 3.47 mm with a 95% CI of [3.40 mm, 3.53 mm] was derived across all sessions and based on eight test locations on the phantom, to which the test probe was navigated. Furthermore, excluding the effects and possible imperfections of the MR image dataset of the measurement phantom on the navigation, a system accuracy of 2.19 mm with a 95% CI of [2.11 mm, 2.26 mm] was obtained. It may be concluded that the achieved results of the TMS Navigator TS are comparable to or better than the values reported from comparable TMS navigation systems, especially the system chosen as predicate device "K191422" (mean system accuracy of 3 mm +/- 2.1 mm when navigating with a hand-held probe and 5 mm +/- 2.1 mm when navigating with a TMS coil).