Re: K183605

Trade/Device Name: Spine & Trauma Navigation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 24, 2019
Received: May 31, 2019

Dear Hugo Morales:

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.


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,

Jesse Muir -S

For, Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
INDICATIONS FOR USE

Spine & Trauma 3D is intended as an intraoperative image-guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on a patient's preoperative or Intraoperative 2D or 3D image data. Spine & Trauma 3D enables computer-assisted navigation of medical image data, which can either be acquired preoperatively or intraoperatively by an appropriate image acquisition system. The software offers screw implant size planning and navigation on rigid bone structures with precalibrated and additional individually-calibrated surgical tools. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.
1 INTENDED USE:

The intended use of the Spine & Trauma Navigation System is to support the surgeon in an operating theater for spinal and trauma cases. The System enables the user to navigate different instruments and/or implants in 3D datasets.

Indications for Use

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2 DEVICE DESCRIPTION:

This navigation system consists of software and hardware components and is an image guided surgery system for navigated treatments in the fields of spine and trauma surgery, whereas the user may use 3D data based on CT, MR or XT. The Software may be installed on a fixed (e.g. Buzz Navigation (CM)) or mobile (e.g. Kick, Curve) navigation platform and supports the surgeon in clinical procedures by displaying tracked instruments in patient's image data. Such instruments can be held by a surgeon or by a mechatronic arm, which passively keeps the instrument in the position. (Mechatronic Vario Guide, “Cirq”).

Operator profile

The operator’s profile for this devices are surgeons or their assistants having a 3D image acquisition system (such as CT or 3D C-arm) in combination with a Brainlab navigation system. All operators are performing surgeries with this system on bony structures (e.g. spine), independent of their original discipline. Therefore different kind of surgeons may perform such procedures, which also includes Orthopedic, Spinal, Trauma and Neuro surgeons.

Patient population

The patient population includes any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, the pelvis, a long bone or vertebra can be identified relative to the acquired image (CT, 3D fluoroscopic image reconstruction).

Intended use environment

The application shall be used in an operating room / suite.

Operating principle

Infrared passive marker based tracking as provided by the optical tracking camera unit of the navigation station is used to determine the instrument's and patient's position. The relation between the patient and the reference attached to the patient is realized with a registration (manually or automatic).

Use scenarios

The system is placed in a way that the surgeon can easily watch the screen(s) and interact with the system during the procedure, but sterility is not compromised. The camera is positioned in a way that it has an unobstructed view on the surgical field.

The patient is positioned and draped in the usual manner, taking in to account that the reference geometry has to be attached to the relevant anatomical structure in a way that it is not disturbing the latter workflow. The surgical approach is performed. A reference array is attached to the relevant bony structure using conventional surgical techniques (either under sight or minimally invasive). The 3D dataset is either acquired or loaded and subsequently registered.
After the scan has been transmitted to the navigation system or the registration computation has been performed, the surgeon is asked to verify the success of the registration with a general instrument or a dedicated pointer.

After successful verification the surgeon is able to access pre-planned objects, to plan or re-plan screws / trajectories and to visualize manually or pre-calibrated surgical instruments.

**Intended part of the body or type of tissue applied to or interacted with**

This system has different components, whereas most of them are software. Therefore, only instruments may get in contact with a patient, some instruments are included to perform the surgery. All Instruments are used temporarily for orientation within the situs or for preparations to be able to implant 3rd party devices, which are not part of this system.

Such instruments can be used at rigid bony structures, such as a long bone or vertebra, where the user wants to use this navigation software according to the indications for use.

**Essential performance characteristics**

The essential performance characteristic for this product is the overall registration and navigation accuracy of the system to ensure the safe and effective use according to the intended use.

### 3 VERIFICATION SUMMARY

The verification of the Spine & Trauma Navigation System has been carried out thoroughly both at the top level and on underlying modules according to the verification plan and following internal processes. The verification was done to demonstrate that the design specifications are met.

In general, verification includes different kinds of tests like Unit Tests within the software, GUI based automatic software tests and explorative testing. Results are documented in corresponding test reports and summarized in the Verification Summary document. For hardware parts, mechanical or biocompatibility tests were performed and filed accordingly.

For the integration of the Mechatronic Vario Guide, hardware and software related tests were performed regarding the following aspects:

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
<th>Conclusion / Result</th>
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<tbody>
<tr>
<td>Verification of general functions</td>
<td>Tests regarding accurate positioning as well as robust alignment of a surgical instrument with the Mechatronic Vario Guide have been conducted on an MIS Spine Training Model in a simulated clinical environment and were performed by spinal surgeons.</td>
<td>Verification of general functions successful. All requirements met.</td>
</tr>
<tr>
<td>General design requirements</td>
<td>Verification of general functions to overall design, layout and general behavior.</td>
<td>Verification of general design requirements successful.</td>
</tr>
<tr>
<td>Safety tests regarding risk analysis</td>
<td>Implementation and effectiveness of all risk control measures specified for the Mechatronic Vario Guide are tested and verified.</td>
<td>Risk control measures are effective and mitigate the associated risks.</td>
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<tr>
<td>Human factors / Usability Testing</td>
<td>Usability tests with surgeons and OR nurses were performed in a simulated clinical environment covering the complete clinical workflow with the Mechatronic Vario Guide in</td>
<td>System is safe and effective to use.</td>
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<tr>
<td><strong>Product safety tests</strong></td>
<td>Compliance of Mechatronic Vario Guide including the Surgical Base System and the drape with AAMI/ANSI ES60601-1:2005/(R)2012 for medical electrical equipment has been tested. Part 1: General requirements for basic safety and essential performance Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests</td>
<td>Compliance with standards requirements demonstrated, no deviations.</td>
</tr>
<tr>
<td><strong>Biocompatibility / Reprocessing</strong></td>
<td>Material properties in relation to biocompatibility and their response to cleaning, disinfection and sterilization have been assessed and tested.</td>
<td>Biocompatibility assessment and reprocessing tests successful.</td>
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<td><strong>Environmental tests</strong></td>
<td>Tests regarding adherence to RoHS, REACH and WEEE directives.</td>
<td>Environmental tests successful.</td>
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<tr>
<td><strong>Integration tests with the spine navigation applications and Brainlab navigation platforms</strong></td>
<td>Verification integration of Mechatronic Vario Guide into the spinal workflow and compatibility tests with the spinal navigation applications and Brainlab navigation platform.</td>
<td>Integration and compatibility tests successful.</td>
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<tr>
<td><strong>Mechanical tests</strong></td>
<td>Mechanical stability tests and interface tests of the components of the Mechatronic Vario Guide from fixating the mechatronic arm to the OR table to holding a drill guide with a defined holding force.</td>
<td>Mechanical tests successful.</td>
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<tr>
<td><strong>Integration tests of Surgical Base System</strong></td>
<td>The Mechatronic Vario Guide integrates the Medineering Surgical Base System. Tested integration of surgical base system into the Mechatronic Vario Guide including verification tests ensuring that the specified braking concept and visual indicators are correctly implemented and that in any position the expected holding forces are met.</td>
<td>Surgical Base System integration tests successful.</td>
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<tr>
<td><strong>Surgical Base System firmware software verification</strong></td>
<td>Tested software according to IEC 62304 and &quot;FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices&quot;</td>
<td>Surgical Base System software verification successful.</td>
</tr>
<tr>
<td><strong>Integration tests of sterile drape</strong></td>
<td>The Mechatronic Vario Guide integrates a drape to ensure sterile environment to the surgical instruments. Tested that the drape matches in form, fit and function with the mechanical dimension onto the components of the Mechatronic Vario Guide, ensures a sterile barrier and is compatible with the navigation.</td>
<td>Drape integration tests successful.</td>
</tr>
</tbody>
</table>

All tests successfully passed demonstrating that the subject device performs as safely and effectively as the predicate device and supporting substantial equivalence.
4 SUBSTANTIAL EQUIVALENCE

The Spine & Trauma Navigation System has similar functionality, intended use, technological characteristics and typical users as the predicate device. Additionally, the Mechatronic Vario Guide ("Cirq") has been included as a holding arm for Drill Guides to support the surgeon in pedicle screw placement procedures. Other included minor changes do not affect the fundamental scientific technology of the device.

5 CONCLUSION

The comparison of the Spine & Trauma Navigation System with the predicate device shows that the Spine & Trauma Navigation System has similar functionality, intended use, technological characteristics, and typical users as the predicate device. Verification and validation activities ensure that the design specifications are met and that the Spine & Trauma Navigation System does not introduce new issues concerning safety and effectiveness. Hence the Spine & Trauma Navigation System is a substantial equivalent to the predicate device.