May 12, 2022

CTL Medical Corporation
℅ Dhaval Saraiya
Regulatory/Quality Consultant
Omni Strategic Solutions, LLC
700 Pennsylvania Ave SE
2nd Floor
Washington, District of Columbia 20003

Re: K213491
Trade/Device Name: CTL Amedica Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 8, 2022
Received: April 12, 2022

Dear Dhaval Saraiya:

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,

Shumaya Ali, M.P.H.
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

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)*
K213491

Device Name
CTL Amedica Navigation Instrument System

Indications for Use *(Describe)*
The CTL Amedica Navigation Instrument System is intended to be used during the preparation and placement of CTL Amedica screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The CTL Amedica Navigation Instrument System is specifically designed for use with the Medtronic StealthStation System, which 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 vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the CTL Amedica Navigation Instrument System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on September 13, 2019.

Sponsor:

CTL Medical Corporation
Sean Suh
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Addison, TX 75001

Contact Person:

Dhaval S.
Omni Strategic Solutions, LLC.
Regulatory/Quality Consultant
Email: omniregsolutions@gmail.com
Tel: 213-400-2576

Date:

11 May 2022

Subject Device:

Trade Name: CTL Amedica Navigation Instrument System
Common Name: Orthopedic Stereotaxic Instrument
Classification Name: OLO – Stereotaxic Instrument (21 CFR 882.4560)

Predicate Device(s):

Primary	K172115	Navigated Instrument System	Orthofix Inc.
	K153442	Medtronic Navigated Manual Reusable Instruments for Use with StealthStation	Medtronic

Purpose and Device Description:

The purpose of this submission is to request clearance for the new CTL Amedica Navigation Instrument System.
The CTL Amedica Navigation Instrument System are manual surgical instruments for use with the Medtronic® StealthStation™ Navigation System to assist surgeons in precisely locating

anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. This surgical imaging technology provides surgeons visualization for complex and MIS procedures and confirms the accuracy of advanced surgical procedures. Use of this navigation system provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement.

The Navigation Instruments include the following:

- Drivers
- Taps
- Awls
- Probes

Use of the Navigated Instrument System is limited to Taps ranging in sizes from 4.5mm to 8.5mm in diameter. The Navigation Instruments are to be used with the following CTL Amedica Systems but not limited to:

- RAPHAEL™ Pedicle Screw System Family
- PICASSO II™ MIS Spinal System Family
- TAURUS™ Pedicle Screw System Family

The CTL Amedica Navigation Instruments are designed for use only with the hardware and software of the Medtronic StealthStation Navigation System.

The CTL Amedica Navigation Instruments are manufactured from Stainless Steel and Aluminum. All of these materials conform to ASTM F899.

Intended Use and Indications for Use:

The CTL Amedica Navigation Instrument System is intended to be used during the preparation and placement of CTL Amedica screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The CTL Amedica Navigation Instrument System is specifically designed for use with the Medtronic StealthStation System, which are 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 vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The intended use is similar to the intended use cleared in K172115 and K153442.
- **Indications for Use:** The indications for use are similar to the indications for use cleared in K172115 and K153442.
- **Materials:** The CTL Amedica Navigation Instrument System are manufactured from Stainless Steel (per ASTM F899) and Aluminum (per ASTM B221) which are commonly used materials in orthopedic instruments and similar to materials used in K172115 and K153442.
- **Design Features:** The design features for the CTL Amedica Navigation Instrument System is similar to those in currently marketed devices cleared in K172115 and K153442. The design differences have not identified any issues that would impact the safety and effectiveness of the device.
- **Sterilization:** The CTL Amedica Navigation Instrument System are offered to the user in the non-sterile configuration. The non-sterile instruments will be required to be steam sterilized by the user prior to use is similar to the devices cleared in K172115 and K153442.

Summary of Performance Data (Nonclinical and/or Clinical):

- **Non-Clinical Tests:**
  - **Compatibility Testing** - Testing included physical testing with all subject instruments to demonstrate that the subject instruments can be regsitered with the StealthStation system and are compatible with the StealthStation system software in terms of accuracy, function and performance in a simulated surgical navigation use environment
  - **Dimensional Comparison** - Engineering analysis and tolerance analysis included dimensional measurements and geometrical comparisons of both the predicate devices and subject devices
  - **Rigidity Comparison** – Testing to demonstrate that the NavLock engagement feature on the subject instruments is equivalent to the predicate engagement feature

  The non-clinical testing demonstrated that the subject instruments registered successfully with the StealthStation system and are substantially equivalent to the predicate devices with regards to compatibility, accuracy, function and performance. Therefore, it can be concluded that the compatibility, accuracy, function, and performance of the subject devices are substantially equivalent to the predicate devices.
- **Clinical Tests:**
  - N/A

Substantial Equivalence Conclusion:	The CTL Amedica Navigation Instrument System has shown to be substantially equivalent to the predicate device with regards to indications, design, technology, funcitionality and performance. Results of the non-clinical tests indicate that the device will perform within the intended uses and no new issues of safety and effectiveness have been raised.