



October 27, 2023

CoreLink, LLC
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K231494

Trade/Device Name: CoreLink Robotic Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 27, 2023
Received: October 27, 2023

Dear Nathan Wright:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming

product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

510(k) Number (if known)

K231494

Device Name

CoreLink Robotic Navigation Instruments

Indications for Use (Describe)

CoreLink Robotic Navigation Instruments are indicated to be used during the preparation screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures for skeletally mature patients, where reference to a rigid anatomical structure such as vertebra can be identified. These instruments are designed for use with the Globus ExcelsiusGPS system, which is indicated for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.

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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K231494 - 510(K) SUMMARY

Submitter's Name:	CoreLink, LLC
Submitter's Address:	2072 Fenton Logistics Park St. Louis, Missouri 63026
Submitter's Telephone:	888-349-7808
Contact Person:	Nathan Wright MS, RAC Empirical Technologies 1-719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	October 27, 2023
Trade or Proprietary Name:	CoreLink Robotic Navigation Instruments
Device Classification Name:	Orthopedic Stereotaxic Instruments
Classification & Regulation #:	Class II per 21 CFR §882.4560
Product Code:	OLO
Classification Panel:	Orthopedic – Stereotaxic, Trauma, and Restorative Devices (DHT6C)



DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

CoreLink Robotic Navigation Instruments are non-sterile, reusable instruments including taps and drivers that can be operated manually. These instruments are intended to be used with the Globus Medical Excelsius GPS® Robotic Navigation Platform to aid in implantation of CoreLink Pedicle Screw System implants (NextGen Pedicle Screw System, CoreLink Midline Fixation System (CentraFix), and Tiger Spine System). The instruments are manufactured from stainless steel.

INDICATIONS FOR USE

CoreLink Robotic Navigation Instruments are indicated to be used during the preparation screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures for skeletally mature patients, where reference to a rigid anatomical structure such as vertebra can be identified. These instruments are designed for use with the Globus ExcelsiusGPS system, which is indicated for use as an aid for precisely locating anatomical structures and for the spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. The system is indicated for the placement of spinal and orthopedic bone screws.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of the safety and effectiveness. Specifically, the following characteristic are the similar between the subject and predicates:

- Device design and dimensions
- Indications for use
- Materials of manufacture
- Principles of operation

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K171651	EXCELSIUS GPS	Globus Medical Inc.	OLO	Primary
K221776	NextGen Pedicle Screw System	CoreLink, LLC	NKB	Additional
K210539	CoreLink Midline Fixation System	CoreLink, LLC	NKB	Additional
K133369	Tiger Spine System	CoreLink, LLC	NKB, KWP, MNH, MNI	Additional

PERFORMANCE DATA

The CoreLink Robotic Navigation Instruments have been evaluated through an engineering analysis and geometric comparison to predicate devices to establish the safety and efficacy for accuracy performance.

The results of this engineering analysis show that the subject is substantially equivalent to the cleared predicate.

CONCLUSION

The overall technology characteristics and engineering analysis lead to the conclusion that the CoreLink Robotic Navigation Instruments are substantially equivalent to the predicate device.