December 1, 2022

Circinus Medical Technology, LLC
% Alex Cadotte
Associate Director, Software & Digital Health
MCRA, LLC
803 7th St., NW, 3rd Floor
WASHINGTON DC 20001

Re: K213768
Trade/Device Name: Bolt Navigation System ("BNS")
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: October 18, 2022
Received: October 27, 2022

Dear Alex Cadotte:

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,

Lu Jiang 2022.12.01 11:54:38 -05'00'

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
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)*
K213768

Device Name
Bolt Navigation System ("BNS")

Indications for Use *(Describe)*
The Bolt Navigation System assists in the accurate placement of pedicle screws when used in conjunction with an intraoperative fluoroscope. It utilizes intraoperative fluoroscopic and pre- operative MRI or CT axial images to provide surgical planning and navigational telemetry relative to gravity, based on a fixed entry point ascertained by the user and validated by intraoperative fluoroscopic imaging. It is not intended to track patient position. The System is indicated for open and minimally invasive pedicle screw placement using a posterior approach in the thoracolumbar and sacral spine (T-9 to S1) where the patients' relevant rigid anatomical structures can be clearly identified on the imaging.

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) Summary K213768

Device Trade Name: Bolt Navigation System ("BNS")

Common Name: Image-intensified fluoroscopic X-ray system

Manufacturer: Circinus Medical Technology, LLC
4450 Arapahoe Avenue
Suite 1000
Boulder, CO 80303

Contact: Mr. Patrick West
Circinus Medical Technology, LLC
Phone: (207) 651-1334
Email: patrick@boltnav.com

Prepared by: MCRA, LLC
1050 K Street NW, Suite 1000
Washington, DC 20001
Phone: (202) 552-5800

Date Prepared: Oct 25, 2021

Classification: 21 CFR §892.1650

Class: II

Product Codes: OWB

Indications for Use:

The Bolt Navigation System assists in the accurate placement of pedicle screws when used in conjunction with an intraoperative fluoroscope. It utilizes intraoperative fluoroscopic and pre-operative MRI or CT axial images to provide surgical planning and navigational telemetry relative to gravity, based on a fixed entry point ascertained by the user and validated by intraoperative fluoroscopic imaging. It is not intended to track patient position. The System is indicated for open and minimally invasive pedicle screw placement using a posterior approach in the thoracolumbar and sacral spine (T-9 to S1) where the patients' relevant rigid anatomical structures can be clearly identified on the imaging.

Device Description:

The BNS is comprised of the Bolt Navigation Unit (BNU) (an iPod touch® mobile digital device with the Bolt navigation software loaded on it), the Bolt single use case, and sterile drape. The

BNS is intended to provide navigational guidance during spine surgery. The system uses pre- and perioperative imaging data, and input from the surgeon via the BNU touchscreen to construct the proper angular position of the instrumentation and implants relative to gravity, and communicates this information to the surgeon via the BNU screen attached to the instrument allowing the surgeon to look at both the surgical site and the navigation data at the same time, thus attenuating the risk of attention shift.

The BNS provides guidance data by displaying the angular orientation of a surgical instrument (such as a pedicle probe or awl) relative to a surgeon selected entry point on the patient and gravity. Angular orientation of the instruments is linked to the imaging data via the BNS.

The system is intended to be used for both image fusion and navigation for spine surgery applications where reference to relevant rigid structures can be identified relative to a perioperative image data of the anatomy and the gravity vector.

Predicate Device:

The Track X Technology, TrackX Device (K200360) serves as the primary predicate device. The Augmedics xvision Spine System (K190929) and the Medtronic StealthStation (K133444, K170011) serve as reference devices.

Technological Characteristics Comparison:

The BNS and its primary predicate technology are designed to aid the physician in positioning surgical instruments and placing implants by providing visual feedback on the movement of instruments relative to imaging data. Both systems use software platforms that allow for the surgeon to track the surgical instruments relative to the perioperative fluoroscopic images.

Both systems enable the surgeon to view the orientation of surgical instruments relative to that planned by the surgeon on preoperative image data while performing the surgical procedure with the aid of a fluoroscope. The systems provide guidance data by tracking and displaying orientation of the Spinal Instruments relative to a surgeon identified entry point and the gravity vector. Tracking data is linked to the preoperative imaging data.

Both systems are designed to work effectively with a range of 3rd party surgical instruments.

The BNS and the reference devices are designed to provide trajectory orientation guidance to the surgeon relative to relevant rigid anatomical structure with a performance goal of $\leq 3°$. These systems use software platforms that allow for the surgeon to match intraoperative trajectory to pre- and perioperative images and planning based on a surgeon identified entry-point. Both systems enable the surgeon to view the angular orientation of surgical instruments relative to that planned by the surgeon on preoperative image data while performing the surgical procedure. The BNS provides navigational guidance in three-degrees of freedom relative to a chosen entry point and the gravity vector while the reference devices (K190929, K133444, K170011), provide navigational guidance relative to a frame attached to the patient in six-degrees of freedom.

Nonclinical Testing:

Verification/Validation activities and performance testing have been conducted to support that the subject device meets the performance requirements under the indications for use conditions and to support substantial equivalence to the predicate devices, including the following:

- Sterilization, Cleaning, and Shelf-life Validation
- Biocompatibility Evaluation
- Non-Clinical Software Documentation and Verification
- Non-Clinical Cybersecurity Evaluation
- Electrical safety and EMC testing (IEC 60601-1 and IEC 60601-1-2)
- Usability Validation testing per IEC 62366-1: 2015, IEC 62366-2ANSI/AAMA HE75 and FDA Guidance for Industry and FDA Staff, including a Surgeon- Performed Cadaveric Study
- Non-Clinical Accuracy Testing per ASTM F2554-10
- Cadaveric Trajectory Accuracy Study, based on a protocol that was discussed and reviewed by FDA via Submission Issue Request on July 12, 2022(Q220500/S001)

Clinical phantom accuracy results

Mean	Std. Deviation	95% CI of Mean	95% CI of Individuals	99% CI of Mean	99% CI of Individuals
0.35°	0.20°	0.39°	0.69°	0.41°	0.82°

CI (Confidence Interval)

Cadaveric accuracy results

Planned trajectory vs actual placement accuracy (≤ 3˚ / 95% CI)

	Estimate	**2-sided 95% CI LB**	**2-sided 95% UB**	**1-sided 95% UB**
Parametric*	1.59	1.31	1.86	1.81
Non-Parametric+	1.78	1.62	2.12	2.07
Notes: *Overall mean accuracy error estimate and 2-sided 95% CI and 1-sided 95% CI based on t-student distribution. + Overall median accuracy error estimate and non-parametric distribution-free (bootstrap) 2-sided 95% CI and 1-sided 95% CI. Testing included levels T9 to S1				

CI (Confidence Interval)

The analysis demonstrates that source-specific variability is small and the overall angle accuracy performance with a mean of 1.59° with a 95% CI of being statistically significantly lower than 3 degrees.

Clinical Testing:

Circinus has conducted a multi-surgeon clinical study. A summary report for this study has been included at the request of the FDA and is intended as supplementary information for the Agency's reference and to provide the Agency further evidence that the subject device performs as intended in its intended clinical application.

Conclusion:

The BNS is substantially equivalent to the predicate device(s) with respect to its indications for use, design, and function.