January 10, 2024

Zeta Surgical Inc
Roman Stolyarov, Ph.D.
Chief Product Officer
115 Kingston Street, Floor 2
Boston, Massachusetts 02111

Re: K233903
Trade/Device Name: Zeta Cranial Navigation System (ZNS131-US)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: December 11, 2023
Received: December 11, 2023

Dear Dr. Stolyarov:

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,

Adam D. Pierce -S
Digitally signed by Adam D. Pierce -S
Date: 2024.01.10 12:34:35 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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)*
K233903

Device Name
Zeta Cranial Navigation System (ZNS131-US)

Indications for Use *(Describe)*
The Zeta Cranial Navigation System is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical instruments used by surgeons. The device is indicated only for cranial surgery where reference to a rigid anatomical structure can be identified, does not require rigid fixation of the patient, and does not require fixation of a navigated instrument guide to the patient. The system is intended to be used in operating rooms and in less acute surgical settings such as interventional procedure suites.

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 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Zeta Cranial Navigation System is provided below.

1. SUBMITTER

Applicant: Zeta Surgical Inc.
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Boston, MA 02111

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Date Prepared: January 10, 2024

2. DEVICE

Device Trade Name:	Zeta Cranial Navigation System
Device Common Name:	Neurological Stereotaxic Instrument
Classification Name	Stereotaxic instrument, 21 CFR 882.4560
Regulatory Class:	Class II
Product Code:	HAW

3. PREDICATE DEVICE

Predicate Device: Zeta Cranial Navigation System [K230661]

4. DEVICE DESCRIPTION

The Zeta Cranial Navigation System is a stereotaxic, image guided planning and intraoperative guidance system enabling computer-assisted cranial interventional procedures. The system assists surgeons with the precise positioning of surgical instruments relative to patient anatomy by displaying the position of navigated surgical instruments relative to 3D preoperative medical scans.

5. INDICATIONS FOR USE

The Zeta Cranial Navigation System is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical instruments used by surgeons. The device is indicated only for cranial surgery where reference to a rigid anatomical structure can be identified, does not require rigid fixation of the patient, and does not require fixation of a navigated instrument guide to the patient. The system is intended to be used in operating rooms and in less acute surgical settings such as interventional procedure suites.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Subject Device	Predicate Device
The Zeta Cranial Navigation System is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical instruments used by surgeons. The device is indicated only for cranial surgery where reference to a rigid anatomical structure can be identified, does not require rigid fixation of the patient, and does not require fixation of a navigated instrument guide to the patient. The system is intended to be used in operating rooms and in less acute surgical settings such as interventional procedure suites.	*The Zeta Cranial Navigation System is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical instruments used by surgeons. The device is indicated only for cranial surgery where reference to a rigid anatomical structure can be identified, does not require rigid fixation of the patient, and does not require fixation of a navigated instrument guide to the patient. The system is intended to be used in operating rooms and in less acute surgical settings such as interventional procedure suites.*

Technological Comparisons

The table below compares the key technological features of the subject device to the predicate device (Zeta Cranial Navigation System, K230661).

Table 1: Technological Comparison

	Cleared Device	Subject Device
General		
510(k) Number	K230661	K233903
Device Name	Zeta Cranial Navigation System	Zeta Cranial Navigation System
Classification Regulation	21 CFR 882.4560	21 CFR 882.4560
Product Code	HAW	HAW

510(k) Summary

	Cleared Device	Subject Device
Classification	Class II	Class II
Indications For Use	The Zeta Cranial Navigation System is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical instruments used by surgeons. The device is indicated only for cranial surgery where reference to a rigid anatomical structure can be identified, does not require rigid fixation of the patient, and does not require fixation of a navigated instrument guide to the patient. The system is intended to be used in operating rooms and in less acute surgical settings such as interventional procedure suites.	The Zeta Cranial Navigation System is a stereotaxic image guidance system intended for the spatial positioning and orientation of neurosurgical instruments used by surgeons. The device is indicated only for cranial surgery where reference to a rigid anatomical structure can be identified, does not require rigid fixation of the patient, and does not require fixation of a navigated instrument guide to the patient. The system is intended to be used in operating rooms and in less acute surgical settings such as interventional procedure suites.
Intended User	Neurosurgeons and neurosurgical procedure staff	Neurosurgeons and neurosurgical procedure staff
Intended Use Environment	Neurosurgical operating room and facilities equipped for interventional cranial procedures	Neurosurgical operating room and facilities equipped for interventional cranial procedures
Anatomical Site	Head	Head
Principle of Operation	Preoperative image upload, Surgical planning, Patient registration, and Instrument guidance	Preoperative image upload, Surgical planning, Patient registration, and Instrument guidance
Technology		
Accepted Imaging Modalities	3D DICOM CT and MRI	3D DICOM CT and MRI
Data Input	USB and CD-ROM	USB and CD-ROM
Instrument Tracking Technology	Optical tracking of wireless, unpowered instruments	Optical tracking of wireless, unpowered instruments
Instrument Compatibility	Brainlab Disposable Stylet only	Brainlab Disposable Stylet only
Registration Technology	Structured light and machine vision	Structured light and machine vision
Guidance Technology	Image based, provides real-time display of instrument position relative to patient anatomy	Image based, provides real-time display of instrument position relative to patient anatomy
Major System Components	Cart, Sensor head, Sensor head positioning arm, Monitor, Monitor positioning arm, Tracked instruments, Software	Cart, Sensor head, Sensor head positioning arm, Monitor, Monitor positioning arm, Tracked instruments, Software
User Interface	Non-sterile touchscreen monitor that is covered with a transparent sterile cover during the procedure	Non-sterile touchscreen monitor that is covered with a transparent sterile cover during the procedure
Workflow Components	Upload, Segmentation, Planning, Staging/Positioning, Registration, Instrument Calibration, Navigation	Upload, Segmentation, Planning, Staging/Positioning, Registration, Instrument Calibration, Navigation
Planning Features	Multiple target point selection, multiple instrument selection	Multiple target point selection, multiple instrument selection
Navigation	Target point projection, instrument rendering,	Target point projection, instrument rendering,

510(k) Summary

	Cleared Device	Subject Device
Features	instrument extended trajectory, physical distance measurement, multiple perspectives	instrument extended trajectory, physical distance measurement, multiple perspectives
Registration Method	Automatic, pinless, and markerless	Automatic, pinless, and markerless
Navigation Frames per Second	5Hz	Uncapped (mean 21fps)
Component and accessory modifications		
Instrument Tracker	NDI Polaris Vicra	NDI Polaris Lyra
3D Camera	Ensenso N35-804-16-IR	Ensenso N36-804-16-IR
Suggested draping accessories	Welmed Protect5 Fenestrated Drape	Welmed Protect5 Fenestrated Drape and Exact Cranial Drape
Other modification		
Instrument calibration	Required	Recommended for Brainlab Disposable Stylet

7. PERFORMANCE DATA

Biocompatibility Testing

There are no direct or indirect patient-contacting components of the subject device. Therefore, patient contact information is not needed for this device.

Electrical safety and electromagnetic compatibility (EMC)

The Zeta Cranial Navigation System was tested in accordance with the following standards:

- IEC 60601-1:2005 (3rd ed) + CORR. 1:2006 + CORR.2:2007+A1:2012 *Medical electrical equipment: Part 1: General requirements for basic safety and essential performance* including US deviations, with the exception of Clause 11.7 regarding biocompatibility. The device passed all tests.
- IEC 62304:2006+ Amd 1:2015, *Medical device software - Software life cycle processes*. The device passed all tests.
- IEC 60601-1-2:2014+A1:2021, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests. The device passed all tests.
- IEC 60601-1-6, Edition 3.2 2020-07, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability. The device passed all tests.

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation provided as recommended by FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. The software for this device was considered a Major level of concern.

Cybersecurity documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*.

Sterilization, Cleaning, and Shelf Life

Sterilization and Cleaning

The device is reusable, provided non-sterile, and is not sterile when used. Cleaning instructions are provided in the labeling.

Shelf-Life

Shelf-life is not applicable due to the low likelihood of time-dependent product degradation.

Bench Testing

The following bench testing was performed to demonstrate substantial equivalence:

- Accuracy testing under different conditions, including:
    - Simulated clinical procedures using virtual targets that can be located only with the guidance system
    - Surgical illumination levels

- Dynamic patient motion
- Other worst-case physical and environmental conditions

- Design validation testing
- Human factors testing, following the FDA Guidance Document, "Applying Human Factors and Usability Engineering to Medical Devices"

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

8. CONCLUSION

The results of testing described above demonstrate that the Zeta Cranial Navigation System is as safe and effective as the predicate device and supports a determination of substantial equivalence.