May 1, 2026

Zeta Surgical, Inc.
Hieu Le Mau, COO
280 Summer St., Floor 7
Boston, Massachusetts 02210

Re: K253663
Trade/Device Name: Zeta Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: November 20, 2025
Received: November 20, 2025

Dear Hieu Le Mau:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JAIME RABEN -S

Jaime Raben, PhD
Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine 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)*
K253663

Device Name
Zeta Navigation System

Indications for Use *(Describe)*

Zeta Navigation System

The Zeta 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.

Zeta Stylet

The Zeta Stylet is intended to be used in conjunction only with the Zeta Navigation System to provide stereotaxic guidance for the placement and operation of catheters, shunts or similar products, and anatomy registration during cranial procedures.

Zeta Bolt

The Zeta Bolt is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction only with the Zeta Navigation System using preoperative MR and/or CT imaging. These procedures include brain biopsies.

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.

Submission: K253663

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for the Zeta Navigation System, the Zeta Stylet and the Zeta Bolt is provided below.

1. SUBMITTER

Applicant:	Zeta Surgical Inc. 280 Summer Street, Floor 7 Boston, MA 02210
Contact:	Hieu Le Mau Chief Operating Officer Zeta Surgical Inc. 280 Summer Street, Floor 7 Boston, MA 02210 +1 (857) 225-4138 hieu.lemau@zetasurgical.com
Prepared on:	4/30/2026

2. DEVICE

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

3. PREDICATE DEVICE

Zeta Navigation System [K242351]
Medtronic Passive Planar Blunt Probe [K050438]
Cranial Reducing Tubes [K162604]

4. DEVICE DESCRIPTION

The Zeta 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. Zeta OS is the software application of the Zeta Navigation System.

The Zeta Stylet is a guiding stylet to be used in conjunction with the Zeta Navigation System for navigated placement of catheters, shunts or similar devices during cranial procedures. The instrument is single-use and not intended for reprocessing or reuse.

The Zeta Bolt is an instrument to be used in conjunction with the Zeta Navigation System for navigated placement of surgical instruments, including brain biopsy needle, using preoperative MR and/or CT imaging. The instrument is single-use and not intended for reprocessing or reuse.

5. INDICATIONS FOR USE

The Zeta 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 Stylet is intended to be used in conjunction only with the Zeta Navigation System to provide stereotaxic guidance for the placement and operation of catheters, shunts or similar products, and anatomy registration during cranial procedures.

The Zeta Bolt is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction only with the Zeta Navigation System using preoperative MR and/or CT imaging. These procedures include brain biopsies.

6. SUBSTANTIAL EQUIVALENCE

The table below compares the key technological features of the Zeta Navigation System to the predicate device (Zeta Navigation System, K242351).

	PREDICATE DEVICE	SUBJECT DEVICE
510(K) NUMBER	K242351	K253663
DEVICE	Zeta Cranial Navigation System	Zeta Navigation System
CLASSIFICATION REGULATION	21 CFR 882.4560	21 CFR 882.4560
PRODUCT CODE	HAW	HAW
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.

	PREDICATE DEVICE	SUBJECT DEVICE
INTENDED USER	Neurosurgeons, neurosurgical procedure staff	Neurosurgeons, neurosurgical procedure staff
INTENDED USE ENVIRONMENT	Neurosurgical operating room, facilities equipped for interventional cranial procedures	Neurosurgical operating room, 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
ACCEPTED IMAGING MODALITIES	3D DICOM CT and MRI	3D DICOM CT and MRI
DATA INPUT	USB, CD-ROM, and PACS	USB, CD-ROM, PACS, and Zeta Cloud
INSTRUMENT TRACKING TECHNOLOGY	Optical tracking of wireless, unpowered instruments	Optical tracking of wireless, unpowered instruments
INSTRUMENT COMPATIBILITY	Brainlab Disposable Stylet, IZI Disposable Passive Blunt Probe	Brainlab Disposable Stylet, IZI Disposable Passive Blunt Probe, Zeta Stylet, Zeta Bolt
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, cloud pre-planning app
NAVIGATION FEATURES	Target point projection, instrument rendering, instrument extended trajectory, physical distance measurement, multiple perspectives	Target point projection, instrument rendering, instrument extended trajectory, physical distance measurement, multiple perspectives
REGISTRATION METHOD	Automatic, pinless, and markerless	Automatic, pinless, and markerless

The table below compares the key technological features of the Zeta Stylet to the predicate device (Medtronic Passive Planar Blunt Probe, K050438).

	PREDICATE DEVICE	SUBJECT DEVICE
510(K) NUMBER	K050438	K253663
DEVICE	Medtronic Passive Planar Blunt Probe	Zeta Stylet
DEVICE TYPE	Slender, rod-like, hand-held manual surgical instrument (metal probe/stylet)	Slender, rod-like, hand-held surgical stylet (metal instrument)
INTENDED USE	Aid for precisely locating anatomical structures in open or percutaneous neurosurgical procedures, for any medical condition where stereotactic surgery is appropriate	The Zeta Stylet is intended to be used in conjunction only with the Zeta Navigation System to provide stereotaxic guidance for the placement and operation of catheters, shunts or similar products, and anatomy registration during cranial procedures
FDA CLASSIFICATION	Class II	Class II
REGULATION	21 CFR 882.4560 — Neurological Stereotaxic Instrument	21 CFR 882.4560 — Neurological Stereotaxic Instrument
PRODUCT CODE	HAW	HAW
PRIMARY MATERIAL	Stainless steel	Titanium (grade 23)
NAVIGATION TECHNOLOGY	Passive optical (reflective sphere markers) — compatible with Medtronic StealthStation electromagnetic/optical navigation systems	Passive optical — compatible with Zeta Navigation System
SINGLE-USE OR REUSABLE	Reusable	Single use
STERILITY	Non-sterile	Non-sterile

The table below compares the key technological features of the Zeta Bolt to the predicate device (Cranial Reducing Tubes, K162604).

	PREDICATE DEVICE	SUBJECT DEVICE
510(K) NUMBER	K162604	K253663
DEVICE	Cranial Reducing Tubes	Zeta Bolt
INTENDED USE	The Cranial Reducing Tubes are intended to maintain the position of instruments or devices placed using stereotactic guidance during planning and operation of neurological procedures performed in conjunction with the use of the Medtronic StealthStation System Image Guided Workstation. The devices were not tested for MR compatibility and are not intended for use in an MRI environment.	The Zeta Bolt is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction only with the Zeta Navigation System using preoperative MR and/or CT imaging. These procedures include brain biopsies.
FDA CLASSIFICATION	Class II	Class II
REGULATION	21 CFR 882.4560 — Neurological Stereotaxic Instrument	21 CFR 882.4560 — Neurological Stereotaxic Instrument
PRODUCT CODE	HAW	HAW
PRIMARY MATERIAL	Stainless steel	Titanium (grade 23)
STERILITY	Non-sterile	Non-sterile
REUSABLE/SINGLE USE	Reusable	Single Use
GUIDE FOR INTRUMENTS AND DEVICES	Yes	Yes
TRAJECTORY ALIGNED BY IMAGE GUIDED WORKSTATIONS	Yes	Yes
ABLE TO INTERFACE STEREOTACTIC NAVIGATION TOOL FOR GUIDANCE	Yes, optical tracking	Yes, optical tracking
NAVIGATIONAL PERFORMANCE	Mean Error ≤2.00 mm and ≤2.00º	Mean Error ≤2.00 mm and ≤2.00º
NAVIGATION SYSTEM INTEGRATION	Medtronic StealthStation System Image Guided Workstation	ZETA Navigation System

7. PERFORMANCE DATA

7.1. Biocompatibility Testing

The biocompatibility of all patient contact materials of the Zeta Stylet and Zeta Bolt was verified according to ISO 10993-1:2018 and FDA guidance on the use of ISO 10993-1, September 2023. No new issues of safety or effectiveness were raised.

7.2. Electrical safety and electromagnetic compatibility (EMC)

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

- IEC 60601-1:2005 Ed. 3 + CORR. 1:2006 + CORR.2:2007+A1:2012 *Medical electrical equipment: Part 1: General requirements for basic safety and essential performance* including US deviations, except 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, Ed. 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.

7.3. 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* and *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*.

7.4. Sterilization, Cleaning, and Shelf Life

The Zeta Navigation System is reusable, provided non-sterile, and is not sterile when used. Cleaning instructions are provided in the labeling. Shelf-life is not applicable due to the low likelihood of time-dependent product degradation.

The Zeta Stylet and Zeta Bolt are single use, provided clean and non-sterile, and are required to be sterilized before use. Sterilization and cleaning procedures are provided in the labeling. The subject devices underwent a steam sterilization validation to demonstrate that they can be expected to be sterile and have a sterility assurance level (SAL) of 10^{-6} or greater after processing. All requirements were met, and no new issues of safety or effectiveness were raised. Shelf-life is not applicable since sterilization occurs at point-of-use.

7.5. Bench Testing

The following bench testing was performed to demonstrate substantial equivalence:

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

7.6. Clinical Testing

No clinical testing was required for the subject devices.

8. CONCLUSION

The results of testing described above demonstrate that the Zeta Navigation System, Zeta OS, Zeta Stylet, and Zeta Bolt are as safe and effective as the predicate devices and support a determination of substantial equivalence.