October 10, 2025

Zeta Surgical Inc.
Hieu Le Mau
Chief Operating Officer
280 Summer Street, Floor 7
Boston, Massachusetts 02210

Re: K251927
Trade/Device Name: Zeta Navigation System (ZNS131-US)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SGE, QFF
Dated: August 9, 2025
Received: August 11, 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 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.

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

for Adam D. Pierce, Ph.D.
Assistant 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251927

Device Name
Zeta TMS Navigation System

Indications for Use *(Describe)*
The Zeta TMS Navigation System is a stereotaxic image guidance system intended for accurate positioning of the treatment coil of TMS systems with respect to target brain locations based on data obtained from 3D patient imaging.

The product is intended for use with the MagVenture therapy systems supplied by Tonica Elektronik A/S (Farum, Denmark), more precisely the R30 stimulator, the R30 stimulator with MagOption, the X100 stimulator and the X100 stimulator with MagOption only with following magnetic coils: Cool-B65 RO.

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.

510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for the Zeta TMS Navigation System 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.
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Boston, MA 02210
+1 (857) 225-4138
hieu.lemau@zetasurgical.com

2. DEVICE

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

3. PREDICATE DEVICE

Localite TMS Navigator TS [K223577]

4. DEVICE DESCRIPTION

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

5. INDICATIONS FOR USE

The Zeta TMS Navigation System is a stereotaxic image guidance system intended for accurate position-ing of the treatment coil of TMS systems with respect to target brain locations based on data obtained from 3D patient imaging.

The product is intended for use with the MagVenture therapy systems supplied by Tonica Elektronik A/S (Farum, Denmark), more precisely the R30 stimulator, the R30 stimulator with MagOption, the X100 stimulator and the X100 stimulator with MagOption only with following magnetic coils: Cool-B65 RO.

6. SUBSTANTIAL EQUIVALENCE

	PREDICATE DEVICE	SUBJECT DEVICE
510(K) NUMBER	K223577	K251927
DEVICE NAME	Localite TMS Navigator TS	Zeta TMS Navigation System
CLASSIFICATION REGULATION	21 CFR 882.4560	21 CFR 882.4560
PRODUCT CODE	HAW	SGE, QFF
CLASSIFICATION	Class II	Class II
INDICATIONS FOR USE	The TMS Navigator TS helps users to plan, implement and document treatment involving TMS of the brain. The system provides planning and navigation functions using anatomical MR data. Regions of the brain to be stimulated can be determined on the basis of anatomy, functional areas or by entering previously calculated coordinates from brain atlases. The product is intended for use with the MagVenture therapy systems supplied by Tonica Elektronik A/S (Farum, Denmark), more precisely the R20 and R30 stimulators, the R30 TMS stimulator with MagOption, the X100 stimulator and the X100 stimulator with MagOption only with following magnetic coils: C-100, C-B60, Cool-B65, Cool-B70, Cool D-B80, MC-125, MC-B70, MCF-75, MCF-125, MCF-B65 and MMC-140-II.	The Zeta TMS Navigation System is a stereotaxic image guidance system intended for accurate positioning of the treatment coil of TMS systems with respect to target brain locations based on data obtained from 3D patient imaging. The product is intended for use with the MagVenture therapy systems supplied by Tonica Elektronik A/S (Farum, Denmark), more precisely the R30 stimulator, the R30 stimulator with MagOption, the X100 stimulator and the X100 stimulator with MagOption only with following magnetic coils: Cool-B65 RO.
INTENDED USER	Trained clinical professionals	Trained clinical professionals
INTENDED USE ENVIRONMENT	Clinical environments such as medical offices and outpatient facilities, where TMS is administered under the supervision of qualified medical personnel.	Clinical environments such as medical offices and outpatient facilities, where TMS is administered under the supervision of qualified medical personnel.
PRESCRIPTION USE	Yes	Yes
ANATOMICAL SITE	Head	Head
NEURONAVIGATION PRINCIPLE	Anatomy registered to patient via physical point selection. Instrument tracking done by infrared 3D camera.	Anatomy registered to patient via structured light-based infrared 3D camera. Instrument tracking done by infrared 3D camera.
ACCEPTED IMAGING MODALITIES	MRI	3D DICOM CT, MRI

	PREDICATE DEVICE	SUBJECT DEVICE
MAJOR SYSTEM COMPONENTS	Cart, Sensor head, Sensor head positioning arm, Monitor, Monitor stand, Tracked TMS coil, Software	Cart, Sensor head, Sensor head positioning arm, Monitor, Monitor positioning arm, Tracked TMS coil, Software
WORKFLOW COMPONENTS	Upload, Segmentation, Planning, Staging/Positioning, Registration, Navigation	Upload, Segmentation, Planning, Staging/Positioning, Registration, Navigation
SELECTION OF TARGETS	Regions of the brain to be stimulated can be determined on the basis of anatomy, functional areas or by entering previously calculated coordinates from brain atlases.	Targets can be determined on the basis of anatomy and functional areas.
PLANNING FEATURES	Multiple target point selection, multiple instrument selection	Multiple target point selection, multiple instrument selection
2D VIEWING	Yes: axial, coronal, sagittal slices through configurable cut planes in 3D scene	Yes: axial, coronal, sagittal slices through configurable cut planes in 3D scene
3D VIEWING	Yes: 3D viewing of skin, brain surface and activation maps, using surface rendering techniques	Yes: 3D viewing of skin for segmentation and planning
SCANNER INTERFACE	DICOM import of MR images	DICOM import of MR/CT images
REGISTRATION FEATURES	Manual point selection registered to reference array	Automatic, pinless, and markerless
COMPATIBLE COILS	C-100, C-B60, Cool-B65, Cool-B70, Cool D-B80, MC-125, MC-B70, MCF-75, MCF-125, MCF-B65 and MMC-140-II	Cool-B65 RO
COMPATIBLE NAVIGATED POINTERS	Pointer ST, Pointer MR	IZI Disposable Passive Blunt Probe
SYSTEM ACCURACY FOR TMS COIL TRACKING	Average: 3.47 mm with a 95% CI of [3.40 mm, 3.53 mm] Best Case: 2.19 mm with a 95% CI of [2.11 mm, 2.26 mm]	Standard Case: 0.45mm mean with 99% CI of [0.40 mm, 0.50 mm] Worst Case: 0.93mm mean with 99% CI of [0.75 mm, 1.11 mm]

7. PERFORMANCE DATA

7.1. 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.

7.2. Electrical safety and electromagnetic compatibility (EMC)

The subject device 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 Moderate 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 device 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.

7.5. Bench Testing

Bench testing was conducted to demonstrate substantial equivalence. Accuracy testing was included assessments of single-point accuracy across the TMS coil, accuracy at various coil orientations, relative point-to-point accuracy, accuracy at extreme positions within the measurement volume, and angular accuracy.

7.6. Clinical Testing

No clinical testing was required for the subject device.

8. CONCLUSION

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