NaviFUS Corporation
℅ Arthur Lung
General Manager
12F., No. 246, Sec. 3, Chengde Rd.
Datong Dist., Taipei City, 10367
TAIWAN

May 5, 2022

Re: K211529
Trade/Device Name: NAVIRFA Scope
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO
Dated: March 24, 2022
Received: March 28, 2022

Dear Arthur Lung:

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,

For

Michael D. O’Hara, Ph.D.
Deputy Director
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211529

Device Name
NAVIRFA Scope

Indications for Use *(Describe)*
The NAVIRFA Scope is intended to provide physicians with the trajectory information of needle instruments when used in conjunction with medical ultrasound. Instruments used with the NAVIRFA Scope may include an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or an ablation needle.
The device is intended to be used in needle interventional procedures that already use ultrasound devices for visualization.
The device is intended for prescription use only.

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 K211529

Submitter's Information

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Contact person:	Arthur Lung, General Manager
Date Prepared:	Nov. 30, 2020

Device Information

Trade Name:	NAVIRFA Scope
Common Name:	Needle Tracking system
Classification Name:	Ultrasonic pulsed echo imaging system (21 CFR 892.1560, Product Code: IYO)

Predicate Device

Device Name:	Clear Guide ONE
510(k) Number:	K141806

Device Description

The NAVIRFA Scope utilizes an optical camera and supporting software to integrate the trajectory information of needle instruments towards improving interventional procedures.
The NAVIRFA Scope is fixed onto an ultrasonic transducer. The camera observes and detects the motion of a needle with an attached tracking marker (NAVIRFA Tracking Kit). The needle position is calculated and mapped onto a real-time ultrasonic image via NAVIRFA software.
The NAVIRFA Scope is compatible with the existing ultrasound system Smartus Ext-1m/3m, TELEMED (K163121).

Indication for Use

The NAVIRFA Scope is intended to provide physicians with the trajectory information of needle instruments when used in conjunction with medical ultrasound. Instruments used with the NAVIRFA Scope may include an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or an ablation needle.
The device is intended to be used in needle interventional procedures that already use ultrasound devices for visualization.
The device is intended for prescription use only.

Comparison to Predicate

The following table provides a comparison of the proposed device to the predicate.

Features	Proposed NAVIRFA Scope	Predicate Clear Guide ONE
Indication for use	The NAVIRFA Scope is intended to provide physicians with the trajectory information of needle instruments when used in conjunction with medical ultrasound. Instruments used with the NAVIRFA Scope may include an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or an ablation needle. The device is intended to be used in needle interventional procedures that already use ultrasound devices for visualization.	The Clear Guide ONE is indicated for augmenting the ultrasonic image of an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or ablation needle, and for predicting its future path on a display, which also shows the image of a B-scan (or similar display) of a medical ultrasound imaging system. The device is intended to be used in procedures where ultrasound is currently used for visualization.
Principle of Operation	Optical detection, single camera	Optical detection, stereo camera
Duration of Use	Multi-use camera	Multi-use camera
Optical camera	Rigidly fixed on ultrasonic probe with approx. ±30 deg field of view	Rigidly fixed on ultrasonic probe with approx. ±30 deg field of view
Power source of camera	USB	USB
Tracking instrument	Needle instrument with attached tracking marker	Any needle-like instrument, but need tracking marker for track tip of instrument as well
Instrument information	overlays onto an existing ultrasound image	overlays onto an existing ultrasound image
Software operating platform	Microsoft Windows	Microsoft Windows

The NAVIRFA Scope is viewed as substantially equivalent to the predicate Clear Guide ONE in K141806 because:

- Indication for use:

The proposed indications of use are identical to the predicate device.
Both devices are intended to be used in currently used ultrasound-guided interventional procedures and indicate to enhance the ultrasound image by providing the trajectory information of needle or needle-liked instruments.

- Technological characteristics:

Both NAVIRFA Scope and the predicate device operates using optical detection technology.
Similar to the predicate device, the NAVIRFA Scope consists of multi-used optical camera and overlays instrument positioning data onto an existing ultrasound image through proprietary software algorithms.
Performance data was collected to demonstrate that the NAVIRFA Scope achieves its intended function in a manner that is as safe and as effective as the predicate device

Summary of Non-Clinical Performance Testing

Bench testing was conducted to evaluate the performance characteristics of NAVIRFA Scope. Data of accuracy was collected and showing that the NAVIRFA Scope could accurately achieve its intended use. No clinical data was collected to support a substantial equivalence determination.

The NAVIRFA Scope complies with the following recognized consensus standards:

1. AAMI ES 60601-1:2005/(R)2012 & A1:2012: Medical electrical equipment—Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2: 2014 – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3. ISO 14971: 2019 Medical devices — Application of risk management to medical devices
4. IEC 62304:2006/AMD 1:2015 Medical device software — Software life cycle processes

The results of bench testing demonstrate that the NAVIRFA Scope is as safe and as effective as the predicate device Clear Guide ONE in K141806.

Substantial Equivalence Conclusion

As detailed, the indications for use, technology or principle of operation and performance are substantially equivalent.
The differences between the proposed NAVIRFA Scope and the predicate Clear Guide ONE in K141806 based upon the comparative performance testing we can conclude that there are no new safety or effectiveness concerns and thus the proposed device can be determined to be substantially equivalent to the predicate.