DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 29, 2017

TaiHao Medical Inc.
% Chiu S. Lin, Ph.D.
President
Lin & Associates, LLC
5614 Johnson Avenue
BETHESDA MD 20817

Re: K171309
Trade/Device Name: BR-FHUS Navigation 1.0
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO
Dated: September 20, 2017
Received: September 20, 2017

Dear Dr. Lin:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K171309

Device Name
BR-FHUS Navigation 1.0

Indications for Use *(Describe)*
BR-FHUS Navigation 1.0 is intended as a standalone software device installed on a standalone windows-based computer to assist physicians with tools for electromagnetic tracking of instruments in respect of breast ultrasound images generated from FDA cleared handheld ultrasound devices. The device is not intended to be used in the environment of strong magnetic or electromagnetic fields, such as in Magnetic Resonance Imaging (MRI) room. BR-FHUS Navigation 1.0 is indicated for use as an adjunct to handheld breast ultrasound to assist the physicians in their scanning process. The scanning paths are displayed on a route map and provide quality control of scanning to provide an overall observation of scanning process.

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.

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5. 510(k) Summary of Safety and Effectiveness Information

5.1. Identification of Submitter:

Submitter: TaiHao Medical Inc.

Address: 3F.-8, No.100, Sec. 2, Heping E. Rd., Da'an Dist., Taipei City 106, Taiwan (R.O.C.)

Phone: 886-2-2736-5679

Contact: HSIN HUNG (Simon) LAI

Title: President

Phone: 886-2-2736-5679

Email: simonlai@taihaomed.com

Manufacturer: TaiHao Medical Inc.

US Agent and Contact: Chiu S. Lin, Ph.D.

LIN & ASSOCIATES, LLC

Address: 5614 Johnson Avenue

Bethesda, MD 20817

Phone: (0) 301-591-3895

Email: cslin@lin-associates.com

Date prepared: April 20, 2017

5.2. Identification of Product

Device Trade Name: BR-FHUS Navigation 1.0

Common and Usual Name: Ultrasonic Pulsed Echo Imaging System

Regulation Number: 21 CFR 892.1560

Classification Product Code: IYO

Classification: Class II

Predicate Device: Tractus TissueMapper Image Recording System **(**K131489**)**

5.3. Intended Use / Indications for Use

BR-FHUS Navigation 1.0 is intended as a standalone software device installed on a standalone windows-based computer to assist physicians with tools for electromagnetic tracking of instruments in respect of breast ultrasound images generated from FDA cleared handheld ultrasound devices. The device is not intended to be used in the environment of strong magnetic or electromagnetic fields, such as in Magnetic Resonance Imaging (MRI) room. BR-FHUS Navigation 1.0 is indicated for use as an adjunct to handheld breast ultrasound to assist the physicians in their scanning process. The scanning paths are displayed on a route map and provide quality control of scanning to provide an overall observation of scanning process.

5.4. Technological Characteristics

BR-FHUS Navigation 1.0 requires the following:

- Off-the-shelf PC Computer to run BR-FHUS Navigation 1.0, which meets the following requirements
  - Minimum 500 GB Hard Drive
  - Minimum Intel Core i5 6400 processor
  - Operating System: Windows
  - Minimum 8GB RAM
  - ≥2 HDMI Ports
  - ≥4 USB Ports of USB 2.0 or better
  - Wired Ethernet
- Computer User Interface
  - Keyboard
  - Mouse
  - Display
    - Minimum display size 17”
    - Minimum display resolution 1920*1080

- Off-the-shelf Image Capture Device
  - PCI frame grabber card inserted into computer card slot of computer noted above or USB frame grabber device connected to computer by cable
  - Video cable from ultrasound system to image capture device
- Off-the-shelf 3D electromagnetic tracking system (Ascension Technologies)
  - Sensor position interface electronics (trakSTAR/driveBAY) connected to computer by cable
  - Sensor position transmitter (Mid-Range Transmitter) and electronics connected to trakSTAR/driveBAY by cable
  - Six degrees of freedom (6DOF) sensor (Model 800) and electronics connected to trakSTAR/driveBAY by cables
  - Urethane clip for affixing a 6DOF sensor to ultrasound transducer

5.5. Comparison with Predicate Devices

BR-FHUS Navigation 1.0 is substantially equivalent to Tractus TissueMapper Image Recording System (K131489) with a general intended use for recording ultrasound sequence images with probe's position. Minor technological characteristics differences do not raise any new questions of safety and effectiveness.

The comparison table between our device and the predicate devices is provided below:

	BR-FHUS Navigation 1.0, k TBD	**Tractus TissueMapper Image Recoding System, k131489**
Manufacturer	TaiHao Medical Inc.	Tractus Corporation
Regulation Number	21 CFR 892.1560	21 CFR 892.1560
Regulation Name	Ultrasonic Pulsed Echo Imaging System	Ultrasonic Pulsed Echo Imaging System
Product Code	IYO	IYO
Intended Use / Indications for	BR-FHUS Navigation 1.0 is intended as a standalone	The Tractus TissueMapper Image Recording System is

Use	software device installed on a standalone windows-based computer to assist physicians with tools for electromagnetic tracking of instruments in respect of breast ultrasound images generated from FDA cleared handheld ultrasound devices. The device is not intended to be used in the environment of strong magnetic or electromagnetic fields, such as in Magnetic Resonance Imaging (MRI) room. BR-FHUS Navigation 1.0 is indicated for use as an adjunct to handheld breast ultrasound to assist the physicians in their scanning process. The scanning paths are displayed on a route map and provide quality control of scanning to provide an overall observation of scanning process.	intended to provide physicians with tools for electromagnetic racking of instruments with respect to image data.
User Population	Skilled medical professionals	Skilled medical professionals
Primary Components	Software: Position Sensor Monitoring, Image presentation and recording, user interface. Hardware: Position Sensor Clip (electromagnetic), Sensor Transmitter, Control	Software: Position Sensor Monitoring, Image presentation and recording, user interface. Hardware: Position Sensor Clip (electromagnetic), Sensor Transmitter, Control

	Computer.	Computer.
Accessories	Media storage (USB)	Media storage (USB)
Virtual Navigator Software	Yes	Yes
Primary Application	Small Parts (Breast)	Abdominal, Small Parts (Breast)
Tracking System	Electromagnetic (Ascension)	Electromagnetic (Ascension)
Software	Yes	Yes
3-D Rendering	No	Yes
Supported Imaging Modalities	Ultrasound	Ultrasound
Software Level of Concern	Moderate level of concern	Moderate level of concern
Image Archiving	Yes	Yes
Scanning Path Recording	Yes	Yes
Scanning Quality Control	Yes	No
Performance Testing	Results from software verification and validation testing performed per internal procedures.	From the 510(k) Summary that is available on the FDA database, it appears that no data from performance testing was submitted.

5.6. Performance Data

Performance, Verification and Validation testing for BR-FHUS Navigation 1.0 was performed per internal procedures to ensure that all functional requirements have been met, and that core functions execute as expected. Testing was conducted in-house by trained personnel in a simulated work-environment using breast phantoms to obtain the functional and accuracy test results.

The result of these tests demonstrates that BR-FHUS Navigation 1.0 validation is with in specification. As such, BR-FHUS Navigation 1.0 is as safe and effective as the predicate devices and is substantially equivalent to existing products on the market today.

BR-FHUS Navigation 1.0 indications for use are drawn from the indications for use of a legally marketed predicate device: Tractus TissueMapper Image Recording System. BR-FHUS Navigation 1.0 draws from features of this predicate device. As such, the features provided by BR-FHUS Navigation 1.0 do not in themselves raise new concerns of safety or effectiveness.

In all instances, BR-FHUS Navigation 1.0 functioned as intended and the operation observed was as expected.

5.7. Substantial Equivalence

The intended use, technological characteristics, and major functionality of BR-FHUS Navigation 1.0. is similar to the predicate device. Neither new safety nor new effectiveness issues are introduced during or after using this device. The performance data generated, as described, demonstrates that our device is as safe and effective, as compared to the predicate device. Therefore, we believe BR-FHUS Navigation 1.0 is substantially equivalent to the predicate device.