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

October 20, 2017

Re: K171709
Trade/Device Name: BR-FHUS Viewer 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 31, 2017
Received: August 28, 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,

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)*
K171709

Device Name
BR-FHUS Viewer 1.0

Indications for Use *(Describe)*
BR-FHUS Viewer 1.0 is intended as a standalone software device installed on a standalone windows-based computer to assist physicians with manipulation and analysis tools in reviewing breast ultrasound images. Images and data are previously recorded from various imaging systems and other sources such as calibrated spatial positioning devices. BR-FHUS Viewer 1.0 provides the capability to visualize two-dimensional ultrasound images along with the scanning paths and position information of probe that stored in the DICOM file in advance.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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: May 31, 2017

5.2. Identification of Product

Device Trade Name: BR-FHUS Viewer 1.0

Common and Usual Name: Picture Archiving and Communications System

Regulation Number: 21 CFR 892.2050

Classification Product Code: LLZ

Classification: Class II

Predicate Device: Tractus TissueMapper Reviewer Application **(**K123901**)**

5.3. Intended Use / Indications for Use

BR-FHUS Viewer 1.0 is intended as a standalone software device installed on a standalone windows-based computer to assist physicians with manipulation and analysis tools in reviewing breast ultrasound images. Images and data are previously recorded from various imaging systems and other sources such as calibrated spatial positioning devices. BR-FHUS Viewer 1.0 provides the capability to visualize two-dimensional ultrasound images along with the scanning paths and position information of probe that stored in the DICOM file in advance.

5.4. Technological Characteristics

BR-FHUS Viewer 1.0 is an electronic image review and reporting software program intended to operate on a windows-based computer. The device allows the review of previously recorded ultrasound examinations, which are performed using standard ultrasound systems and other sources such as calibrated spatial positioning devices, the images of which were recorded digitally.

The images are displayed on a computer monitor. The images can be reviewed individually or as a self-playing sequence. The software can adjust the speed of the playback. In addition, the device software allows the user to save the screenshots as DIOM-compatible files and generate electronic reports.

BR-FHUS Viewer 1.0 requires the following:

- Off-the-Shelf PC Computer to run BR-FHUS Viewer 1.0, which meets the following requirements
  - Minimum 500 GB Hard Drive
  - Minimum Intel Core i5 6400 processor
  - Operating System: Windows
  - Minimum 8GB RAM
- Computer User Interface
  - Keyboard
  - Mouse
  - Display
    - Minimum display size 17”

- Minimum display resolution 1920*1080

5.5. Comparison with Predicate Devices

BR-FHUS Viewer 1.0 is substantially equivalent to Tractus TissueMapper Reviewer Application (K123901) with a general intended use for reviewing ultrasound 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 Viewer 1.0, k TBD	**Tractus TissueMapper Reviewer Application, k123901**
Manufacturer	TaiHao Medical Inc.	Tractus Corporation
Device Common Name	Picture archiving and communications system	Picture archiving and communications system
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Regulation Name	Picture archiving and communications system	Picture archiving and communications system
Product Code	LLZ	LLZ
Intended Use / Indications for Use	BR-FHUS Viewer 1.0 is intended as a standalone software device installed on a standalone windows-based computer to assist physicians with manipulation and analysis tools in reviewing breast ultrasound images. Images and data are previously recorded from various imaging systems and other sources such as calibrated spatial positioning devices. BR-FHUS Viewer 1.0 provides the capability to visualize two-	The Tractus TissueMapper Reviewer Application provides two and three dimensional image review, manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. The supported imaging modality is Ultrasound (US). Images and data are received from various imaging systems and other sources such as calibrated spatial positioning

	dimensional ultrasound images along with the scanning paths and position information of probe that stored in the DICOM file in advance.	devices. This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to imaging probes or other tracked devices. This device is intended to assist skilled medical professionals in clinical screening and interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications.
User Population	Skilled medical professionals	Skilled medical professionals
Primary Components	Software: BR-FHUS Viewer 1.0	Software: TissueMapper Reviewer Application
Accessories	Computer (PC) and storage media (USB)	Computer (PC) and storage media (USB)
Primary Application	Breast	Head and neck, breast, thoracic, and abdominal
Software	Yes	Yes
3-D Rendering	No	Yes
Reporting	Yes	Yes
Supported Imaging Modalities	Ultrasound	Ultrasound

Software Level of Concern	Moderate level of concern	Moderate level of concern
Annotate position of instruments	Yes	Yes
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 Viewer 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 phantom to obtain the functional and accuracy test results.

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

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

In all instances, BR-FHUS Viewer 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 Viewer 1.0. are 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 Viewer 1.0 is substantially equivalent to the predicate device.