DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

TaiHao Medical, Inc.
% Chiu S. Lin, Ph.D.
President
LIN & ASSOCIATES, LLC
9223 Cambridge Manor Court
POTOMAC MD 20854

January 15, 2016

Re: K151075
Trade/Device Name: BR-ABVS Viewer 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 15, 2015
Received: December 15, 2015

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 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 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 yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151075

Device Name
BR-ABVS Viewer 1.0

Indications for Use *(Describe)*
BR-ABVS Viewer 1.0 is intended as a standalone software device installed on a standalone windows-based computer to assist the physician to visualize any orientation of three-dimensional (3-D) breast ultrasound images generated by Siemens ACUSON S2000 Automated Breast Volume Scanner, ABVS (cleared in K081148). The software device is indicated for use to assist the physicians in their review and analysis of the 3-D breast ultrasound images generated by ABVS.
Caution: Federal law restricts this device to sale by or on the order of a physician.

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

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

5.1. Identification of Submitter:

Submitter: TaiHao Medical Inc.

Address: 7F., No.410, Sec. 5, Zhongxiao E. Rd., Xinyi Dist., Taipei City 110, Taiwan (R.O.C.)

Phone: 886-2-2858-2357

Contact: HSIN HUNG (Simon) LAI

Title: President

Phone: 886-2-2858-2357

Email: simonlai@taihaomed.com

Manufacturer: TaiHao Medical Inc.

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

LIN & ASSOCIATES, LLC

Address: 9223 Cambridge Manor Court

Potomac, MD 20854 U.S.A.

Phone: (0) 301-591-3895

Email: cslin@lin-associates.com

Date prepared: April 8, 2015

5.2. Identification of Product

Device Trade Name: BR-ABVS Viewer 1.0

Common and Usual Name: Ultrasound Image Display Device

Device Classification Name: Picture Archiving and Communication System

Regulation Number: 21 CFR 892.2050

Classification Product Code: LLZ

Classification: Class II

Classification Panel: Radiology Devices

Manufacturer: TaiHao Medical Inc.

5.3. Predicate Device

This subject software medical device is substantially equivalent to the devices listed below:

Model: ABVS Workplace

Manufacturer: Siemens Medical Solutions

510(k) Number: K092067, cleared on September 18, 2009

5.4. Device Description

BR-ABVS Viewer 1.0 is intended as a standalone software device installed on a standalone windows-based computer to assist the physician to visualize any orientation of three-dimensional (3-D) breast ultrasound images generated by Siemens ACUSON S2000 Automated Breast Volume Scanner, ABVS (cleared in K081148). The software also automatically generates reports to provide the sub-image and location information of markers annotated during the image review.

5.5. Indications for Use

BR-ABVS Viewer 1.0 is intended as a standalone software device installed on a standalone windows-based computer to assist the physician to visualize any orientation of three-dimensional (3-D) breast ultrasound images generated by Siemens ACUSON S2000 Automated Breast Volume Scanner, ABVS (cleared in K081148). The device is indicated for use to assist the physicians in their review and analysis of the 3-D breast ultrasound images generated by ABVS.

5.6. Comparison with Predicate Devices

BR-ABVS Viewer 1.0 is substantially equivalent to ABVS Workplace with a general intended use for viewing and analyzing ultrasound image data to physicians. 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-ABVS Viewer 1.0	**ABVS Workplace**

Manufacturer	TaiHao Medical Inc.	Siemens Medical Solutions
510(k) Number	K151075	K092067
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
Indications for Use	BR-ABVS Viewer 1.0 is intended as a standalone software device installed on a standalone windows-based computer to assist the physician to visualize any orientation of three-dimensional (3-D) breast ultrasound images generated by Siemens ACUSON S2000 Automated Breast Volume Scanner, ABVS (cleared in K081148). The device is indicated for use to assist the physicians in their review and analysis of the 3-D breast ultrasound images generated by ABVS.	ABVS Workplace is intended to display ultrasound images of the breast acquired from B-mode imaging using an automatic or handheld scanning linear transducer. The images may be reviewed and analyzed by the physician. The ABVS Workplace is indicated for use as an adjunct to mammography. The ABVS Workplace is not intended to be used as a replacement for screening.

Functional Capability of Image Processing	BR-ABVS Viewer 1.0 provides visualization of any orientation of 3-D image.	The ABVS Workplace applies post-processing algorithms based on the nipple location. A reverberation removal algorithm determines tissue contact areas. This suppresses reverberation artifacts from the non-contact area. A proprietary adaptive nipple shadow reduction tool analyzes the data volume and enhances structures in the retroareolar area to improve visualization of this typically challenging anatomical region.
Software Design	Image processing techniques	Same
Platform	Window-based	Same
Operating System	Standard PC or review station	Own workstation, which includes IT hardware and pre-installed software
Clinical Application	As an adjunct to mammography screening	Same
Image Type to Be Processed by The Device	Automated breast ultrasound images generated by Siemens ACUSON S2000 Automated Breast Volume Scanner, ABVS (cleared in K081148).	Same
Image Format	DICOM images acquired on Siemens ACUSON S2000 Automated Breast Volume	Same

	Scanner, ABVS	
Automatically Generating Report	Yes	Yes
Performance Testing to Support SE Determination	Results from Software Validation Report of BR-ABVS Viewer 1.0	From the 510(k) Summary that is available on the FDA database, it appears that no data from performance testing were submitted.

5.7. Performance Standards

No applicable FDA performance standards have been issued.

5.8. Software

Software development for BR-ABVS Viewer 1.0 follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards. Appropriate steps have been taken to control all identified risks for this type of image viewing and quantification device.

5.9. Summary of Performance Data to Support Substantial Equivalence

BR-ABVS Viewer 1.0 displays the 3-D image volume by axial, sagittal, and coronal plane according to the anatomical coordinate system to provide an overall observation. The actual image size is obtained by considering the spacings of three axes specified in the standard DICOM tags. TaiHao Medical Inc. has conducted a performance study to validate and assess the performance of BR-ABVS Viewer 1.0 for its-intended use. An actual clinical image generated by a Siemens ACUSON S2000 Automated Breast Volume Scanner in 2014 was used to do the comparison testing between BR-ABVS Viewer 1.0 and the predicate (ABVS Workplace, K092067) in terms of substantial equivalence in 3-D image loading.

5.10. Conclusions

The intended use, technological characteristics, and major functionality of BR-ABVS Viewer 1.0 are similar to the predicate device and no new issues of safety or effectiveness are introduced by using this device. The performance data generated, as described, demonstrates that our software device is as

safe and effective, as compared to the predicate. Therefore we believe BR-ABVS Viewer 1.0 is Substantially Equivalent to the predicate device.