MEDA Co., LTD
℅ Linda Zhang
RA, R & D Department
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Huayuan Industry Development Area
Tianjin, 300384
P.R. CHINA

Re: K213070
Trade/Device Name: MD-320W Ultrasound Biomicroscope
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: September 15, 2021
Received: September 23, 2021

November 18, 2021

Dear Linda Zhang:

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 and Part 809); 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213070

Device Name
MD-320W Ultrasound Biomicroscope

Indications for Use *(Describe)*

MD-320W Ultrasound Biomicroscope is intended to be used in clinical ophthalmology for ultrasonic diagnosis on the anterior segment of eyes.
The device is intended to be used in hospitals and ophthalmology clinics. The operators should be trained professionals and have basic capabilities for PC operation.
It is not allowed to use UBM on patients with eye trauma, inflammation or infection.

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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510(k) SUMMARY

1. Submitter Information

510(k) owner's name: **MEDA Co., Ltd.**
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Date Prepared: September 15, 2021

2. Device Information

Trade Name/Common Name: MD-320W Ultrasound Biomicroscope

Classification Name: Ultrasonic Pulsed Echo Imaging System (IYO)
Diagnostic Ultrasound Transducer (ITX)

Regulatory Class: Class II

Regulation Number: 892.1560; 892.1570

Product Code: IYO; ITX

3. Predicate Devices

Device Name: VuPad Ophthalmic Ultrasound System

510(k) Number: **K140199**

Manufacturer: Sonomed Inc.

4. Device Description

MD-320W Ultrasound Biomicroscope is an ultrasonic imaging system with high-resolution. It consists of AC-DC power adapter, main unit, 50MHz sector scan probe, footswitch, USB cable

and two user-selectable APPs:

MD3XUBM.AP1-C V1.0 APP (included in MD3XUBM-C V1.0) runs on the windows operating system of the PC and allows the user to control probe scanning, image acquisition and display via the PC user interface.

MD3XUBM.AP1-S V1.0 APP (included in MD3XUBM-S V1.0) runs on the operating system of the legally marketed MD-2300S Ultrasonic A/B Scanner for Ophthalmology (K152318) and allows the user to control probe scanning, image acquisition and display via the MD-2300S user interface.

Under the excitation of electric pulse, the 50MHz ultrasound transducer emits ultrasonic pulse into eye and receives reflective echo from the surfaces of different tissue, thus forming real-time two-dimensional image of eye tissue.

5. Indications for Use

MD-320W Ultrasound Biomicroscope is intended to be used in clinical ophthalmology for ultrasonic diagnosis on the anterior segment of eyes.

It is intended to be used in hospitals and ophthalmology clinics. The operators should be trained professionals and have basic capabilities for PC operation.

It is not allowed to use UBM on patients with eye trauma, inflammation or infection.

6. Comparison of Technological Characteristics

The VuPad diagnostic ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurements of axial length for determination of IOL Power.

It has 10MHz A-scan probe and 12.5 MHz, 20 MHz, 35 MHz and 50MHz B-scan probes. The function of the 35MHz and 50MHz probes is also called Ultrasound Biomicroscopy (UBM), which is used to collect live B-scan images of the anterior segment of the eye.

MD-320W Ultrasound Biomicroscope is fundamentally identical to the Ultrasound Biomicroscopy (UBM) capabilities of the VuPad System. The intended usage and method of application for these transducers are the same for both systems.

The subject and the predicate devices (UBM part) are based on the following same technological elements:

Model / Item	Subject Device MD-320W Ultrasound Biomicroscope	Predicate Device VuPad UBM with 50MHz probe
510(K) number		K140199
Intended Use	It is intended to be used in clinical ophthalmology for ultrasonic diagnosis on the anterior segment of eyes.	The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of

		the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power. *The UBM part is used to collect live B-scan images of the anterior segment of the eye. Note: See §8 of 510(K) Summary of K140199.
Modes of Operation	B-Mode	B -Mode
Selectable A-Scan Vector while in B-Scan mode	Yes	Yes
Technology	Visualization by Ultrasound	Visualization by Ultrasound
General Method of Operation	Echoes converted to images on a screen. Measurement made by time delays	Echoes converted to images on a screen. Measurement made by time delays
Digital System	Echoes converted into digital pulses, all operation carried out digitally	Echoes converted into digital pulses, all operation carried out digitally
Probe /Transducer type	probe with sector scanning (Open Pivoting Single-Element)	Open Pivoting Single-Element
Transducer Frequency Range (MHz)	50	35 and 50 for UBM
Internal Storage	≥512GB（Stored in PC）	≥512GB（Stored in tablet PC）
Control Interface	Operator uses PC with keyboard, mouse and footswitch, or MD-2300S with LCD touch screen and footswitch, to collect exam data.	Operator uses tablet PC with LCD touch screen and foot pedal switch to collect exam data,
Data Storage Location	Storage within software database with ability to recall patient exam records	Storage within software database with ability to recall patient exam records
Printer	Any Windows-compatible printer (separate)	Any Windows-compatible printer (separate)
Acoustic output MI < 0.23 $I_{SPTA.3}$ < 17 mW/cm^2 $I_{SPPA.3}$ < 28 W/cm^2	Track 1	Track 1
Compliance standards	IEC 60601-1: 2005, AMD1: 2012; ANSI/AAMI ES 60601-1: 2005(R)2012 and A1: 2012, C1:2009(R)2012 and	IEC 60601 -1,

	A2:2010/(R)2012; IEC 60601-2-37 (ed.2), am1; IEC 60601-1-2: 2014	 IEC 60601-2-37, EN/IEC 60601-1-2 (2001)

The differences of MD-320W Ultrasound Biomicroscope and its predicate device:

Model	**MD-320W Ultrasound Biomicroscope**	**VuPad**
510(K) number		K140199
Intended Use	It is intended to be used in clinical ophthalmology for ultrasonic diagnosis on the anterior segment of eyes.	The VuPad ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system for ophthalmic application, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye, including the measurement of axial length for determination of IOL Power.
Modes of Operation	B-Mode (anterior segment of eyes)	Ophthalmic A and B Scans
B-Scan Lines per Scan	768	256
B-Scan Scan Display Controls	TGC, Adjustable Gain: 1-99dB	Fully adjustable time-varied gain (TVG), baseline, log gain, and exponential gain
Probe /Transducer type	Mechanical Sector Scan Probe (open pivoting single-element)	Sealed Pivoting Single-Element, and Open Pivoting Single-Element for UBM
B-Scan Transducer Frequency.	50 MHz	10, 12.5, 20 MHz; 35, 50 MHz for UBM.
B-Scan Axial Accuracy (Theoretical)	50 MHz: 0.0153mm	50 MHz: 0.0146mm
Hardware Configuration and Components	System consists of AC-DC power adapter, main unit, 50MHz sector scan probe, USB cable and two user-selectable APPs.	System consists of unit with integrated LCD touch screen, A-probe, sealed B-probe, open transducer water path B-probe, calibration cylinder, probe holder, and foot pedal
B-Scan Video Clips	Capture and store 100- frame video clips	Capture and store 50- frame video clips
Display Screen	LCD Panel (10.1" diagonal wide-screen, 1020 x 768 pixel resolution, or	Integrated LCD Panel (10.1" diagonal wide-screen, 1920x1080 pixel resolution)

Model	MD-320W Ultrasound Biomicroscope	VuPad
	14" diagonal wide-screen, 1366 x 768 pixel resolution)	
Dimensions (inches)	1.6x 8.3x9.6	2 x 8x13.3

The VuPad system is a multi-purpose ophthalmic ultrasonic diagnostic system with three relatively independent functions: biometric A-scan (10MHz), B-scan posterior segment imaging (12.5, 20MHz) and B-scan anterior segment imaging - UBM (35, 50MHz).

MD-320W Ultrasound Biomicroscope (UBM) is only used for imaging of the anterior segment of the eye, so it is compared with the UBM part of VuPad.

As can be seen from the above tables, MD-320W's intended use, working principle, structural composition, mode of operation, Probe/Transducer type and compliance standard are substantially equivalent as the UBM part of the predicate device.

The intended use and hardware configuration and components that differ from the predicate device are those outside the UBM function, such as the A-scan for biometrics, and the 12.5MHz, 20MHz Sealed Pivoting Single-Element probe for imaging of the posterior segment of the eye.

The differences in parameters such as Display Screen, Dimensions, B-Scan Video Clips and B-Scan Lines per Scan have no substantial impact on the intended use, safety and effectiveness of the device.

7. Brief Discussion of Non-clinical Tests

The safety and EMC testing were conducted on the MD-320W and the testing results comply with the requirements of IEC 60601-1 and IEC 60601-2-37 for safety and the IEC 60601-1-2 for EMC. The acoustic output parameters comply with the requirements of IEC 60601-2-37 and FDA Guidance on diagnostic ultrasound systems and transducers.

It is recommended to use FDA-cleared disposable sterile water sac which meets the relevant requirements of ISO10993 to contact patients, such as ClearScan Transducer Cover (K080119). The biocompatibility evaluation has been conducted by the manufacturer according to ISO 10993.

The software and essential performance have passed verification and validation, and the results comply with the related requirements as per the FDA Guidance document “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” issued in June 27, 2019.

8. Conclusions

The results of non-clinical tests as well as the software and essential performance verification and validation demonstrate that the MD-320W Ultrasound Biomicroscope is substantially equivalent in safety, effectiveness and performance to the legally marketed predicate device.

While there are some differences between the MD-320W Ultrasound Biomicroscope and its predicate device, they do not affect the safety or effectiveness.