January 9, 2023

Chongqing Sunkingdom Medical Instrument Co., Ltd.
% Shulin Guo
Registration manager
1010, Block A of China Resource Center No.55 of XieJiaWan JiuLongPo
Chongqing, 400050
CHINA

Re: K222787
Trade/Device Name: Sunkingdom Ophthalmic Ultrasound Examination Instrument: SK-3000A, SK-3000B, SK-3000C, SK-2000AP, SK-2000A, SK-2000P
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: September 1, 2022
Received: December 8, 2022

Dear Shulin Guo:

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,

Yanna S. Kang -S

Yanna Kang
Assistant Director
Mammography and Ultrasound Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222787

Device Name
Sunkingdom Ophthalmic Ultrasound Examination Instrument: SK-3000A, SK-3000B, SK-3000C, SK-2000AP, SK-2000A, SK-2000P

Indications for Use *(Describe)*

Sunkingdom Ophthalmic Ultrasound Examination Instrument can be used in ophthalmology clinical application under A(A-scan echography), P(Pachymetry) and B(B-scan echography) operation modes. A-scan echography applies to axial length measurement, including anterior chamber depth, crystal thickness, vitreous length; Pachymetry applies to corneal thickness measurement; and B-scan echography applies to ocular ultrasound imaging.

The device should be operated by doctors or appropriately-trained healthcare professional and should be used in hospitals or large clinics. It is prohibited to use the device on patients with active ocular inflammatory lesions (such as acute conjunctivitis, blepharitis, keratitis, corneal ulcer, dacryocystitis, iridocyclitis etc);and this device cannot be used on fetuses.

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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K222787

510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with 21 CFR 807.92.

Submitter (510K Owner):	Chongqing Sunkingdom Medical Instrument Co., Ltd 35-2, YingTian GuangDian GongGu, CaiJiaGang Industrial Zone, BeiBei District, Chongqing, China Contact Person: Shulin Guo Phone: +86-23-68643990 Fax: +86-23 -68677919 E-Mail: regist01@cqsunkingdom.com Registration #: 3010610157
Official Correspondent:	Dayna Valente 83 Gerber RD West South Windsor Connecticut, 06074, USA Phone: (860)6484906 Fax: (860) 6484906
Date of Preparation:	August 25th, 2022
Proprietary Name:	Sunkingdom Ophthalmic Ultrasound Examination Instrument SK-3000A, SK-3000B, SK-3000C, SK-2000AP, SK-2000A, SK-2000P
Common or Usual Name:	Ultrasonic pulsed echo imaging system
Classification Name:	System, Imaging, Pulsed Echo, Ultrasonic 21CFR 892.1560, 21CFR 892.1570 Class II
Product Code:	IYO, ITX
Review Panel:	Radiology

Predicate Devices

Main predicate device	ODM-2100 & ODM-2200 Ultrasonic A/B Scan system for Ophthalmology
Manufacturer	MEDA CO., LTD
K#	K063433 for 10MHz A scan and 10MHz B scan

Reference device	MD- 1000P Ultrasonic Pachymeter
Manufacturer	MEDA CO., LTD
K#	K121243 for 20MHz P scan

Intended Use/ Indication for use

Sunkingdom Ophthalmic Ultrasound Examination Instrument can be used in ophthalmology clinical application under A(A-scan echography), P(Pachymetry) and B(B-scan echography) operation modes. A-scan echography applies to axial length measurement, including anterior chamber depth, crystal thickness, vitreous length; Pachymetry applies to corneal thickness measurement;and B-scan echography applies to ocular ultrasound imaging.

The device should be operated by doctors or appropriately-trained healthcare professional and should be used in hospitals or large clinics. It is prohibited to use the device on patients with active ocular inflammatory lesions (such as acute conjunctivitis, blepharitis, keratitis, corneal ulcer, dacryocystitis, iridocyclitis etc);and this device cannot be used on fetuses.

Device Description

Sunkingdom Ophthalmic Ultrasound Examination Instrument, models SK-3000A, SK-3000B, SK-3000C, SK-2000AP, SK-2000A, SK-2000P is an ultrasound imaging system intended for use in ophthalmic applications.

Model SK-3000A with A, P, B probes is used to biometric measurement of axial length (including anterior chamber depth, crystal thickness and vitreous length), corneal thickness and to ocular ultrasound imaging.

Model SK-3000B with A, B probes is used to biometric measurement of axial length (including anterior chamber depth, crystal thickness and vitreous length) and to ocular ultrasound imaging.

Model SK-3000C with B probe is used to ocular ultrasound imaging.

Model SK-2000AP with A, P probes is used to biometric measurement of axial length (including anterior chamber depth, crystal thickness and vitreous length) and corneal thickness.

Model SK-2000A with A probe is used to biometric measurement of axial length (including anterior chamber depth, crystal thickness and vitreous length).

Model SK-2000P with P probe is used to biometric measurement of corneal thickness.

Among them, the 10 MHz A probe transmits ultrasound wave into eye tissue, and measure the duration of the acoustic pulse from the A probe to anterior chamber, lens and vitreum and back to the A probe. This mode is mainly used for biometric measurement axial length, which including anterior chamber depth, lens thickness, vitreous depth of eyes.

The 10 MHz B probe transmits ultrasound wave into eye tissue, and to form a sectional echogram by means of the brightness of echogenic dots. This mode is mainly used for ocular ultrasound imaging.

The 20 MHz Pachymeter probe is to get the thickness of corneal by measurement of the time interval between the anterior and posterior interface reflection waves of cornea. This mode is mainly used for biometric measurement of corneal thickness.

All probes can work independently, and record patient data and connect to a video printer to print image report. It also can work with computer which has the software installed to manage patient record.

This device must be used by trained and qualified medical personnel.

Contraindication: Patients with active ocular inflammatory lesions (such as acute conjunctivitis, blepharitis, keratitis, corneal ulcer, dacryocystitis, iridocyclitis etc) and the fetal cannot use the device.

Technological characteristics

B mode:

Nominal frequency: 10MHz

Detection depth: ≥50mm

Lateral Resolution: ≤ 0.4mm

Axial resolution: ≤0.2mm

Horizontal geometric position accuracy: ≤ 10%

Vertical geometric location accuracy: ≤5%

Blind zone: ≤4mm

Scan Mode: Magnetic drive motor

Gain range: 0- 105dB

Gray Levels: 256

Angle of scan: 53°

Image Freezing: 20 pcs

Display Mode: B, B＋A

Frame rate: ≥ 12 frames/s

A mode:

Nominal frequency: 10MHz

Measurement error: ≤ 0.05mm

Measurement Range: no narrower than 15mm~35mm

Gain range: 0-99dB

IOL Calculation: 6 different calculation formulas

Calculation Method: mean, standard Deviation

Pachymeter:

Nominal frequency: 20MHz

Measurement error: ≤0.01mm

Measurement: Range: no narrower than 0.3mm ~1.5mm

Gain range: 0-99dB

Other Parameter:

Ambient temperature: 5℃ ~ 40℃

Relative humidity: ≤85%

Atmospheric pressure: 700 hPa ~ 1060 hPa

Power supply: AC100-240 V, 50/60 Hz

Substantial Equivalence Disscussion

The Sunkingdom Ophthalmic Ultrasound Examination Instrument SK-3000A, SK-3000B, SK-3000C, SK-2000AP, SK-2000A, SK-2000P are substantially equivalent to the main predicate device ODM-2100&ODM-2200 Ultrasonic A/B Scan system for Ophthalmology and reference predicate device MD- 1000P Ultrasonic Pachymeter, as they have the exactly same indication for use, working principle, also Sunkingdom Ophthalmic Ultrasound Examination Instrument use similar technology and perform similar functions to provide the physician with the intraocular pressure to make a diagnosis.

The Sunkingdom Ophthalmic Ultrasound Examination Instrument SK-3000A, SK-3000B, SK-3000C, SK-2000AP, SK-2000A, SK-2000P has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicates.

Comparison of the predicate device

Device features	Main Predicate device	Reference Predicate device	Subject device
	ODM-2100& ODM-2200 Ultrasonic A/B Scan system for Ophthalmology	MD- 1000P Ultrasonic Pachymeter	Sunkingdom Ophthalmic Ultrasound Examination Instrument SK-3000A, SK-3000B, SK-3000C, SK-2000AP, SK-2000A, SK-2000P
510k number	K063433	K121243	K222787
Product code	IYO, ITX	IYO, ITX	Same
Intended use	To location and visualization of ophthalmic disorders and measurement of ocular distances	To measure corneal thickness.	Same
General description	Diagnostic ultrasound system.To acquire ultrasound data and to display the data in A, B modes of operation.	Diagnostic ultrasound system. To acquire ultrasound data and to display the data in P mode of operation.	Diagnostic ultrasound system. To acquire ultrasound data and to display the data in A, B, P modes of operation.

Patient contact materials	A, B probe	P probe	A, B, P probe
Biocompatibility	All Probes tested for biocompatibility under ISO 10993	All Probes tested for biocompatibility under ISO 10993	same
Working principal	Ultrasound transmission	Ultrasound transmission	Same
Imaging modes	A, B mode	P mode	A, B, P mode
Track	Track 1	Track 1	Same
Acoustic output within FDA guideline	IEC 60601-2-37	IEC 60601-2-37	Same
General safety	IEC 60601- 1, IEC 60601- 1-2	IEC 60601- 1, IEC 60601- 1-2 IEC 60601-2-37	Same: IEC 60601- 1, IEC 60601- 1-2 IEC 60601-2-37
labeling	Conforms to 21CRF part 801	Conforms to 21CRF part 801	Same

Performance Data

The following performance testing was completed to support the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the patient contact material (A probe, B probe, P P probe) of Sunkingdom Ophthalmic Ultrasound examination instrument was conducted accordance with the 21 CFR 58 Good Laboratory Practice for Nonclinical Laboratory Studies,

ISO 10993- 10:2010 Biological Evaluation of Medical Devices-Part 10: Tests For Irritation and Skin Sensitization
ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests For In Vitro Cytotoxicity As recognized by FDA

The A probe, B probe and P probe of Sunkingdom Ophthalmic Ultrasound examination instrument of testing included the following tests:

- In Vitro Cytotoxicity
- Irritation
- Skin Sensitization

The extract of applied sample is not cytotoxic in the framework of ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests For In Vitro Cytotoxicity.

No obvious evidence of skin sensitization was observed for the polar and non-polar extracts of the test item, in accordance with ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10: Tests For Irritation and Skin Sensitization.

Electromagnetic compatibility and electrical safety testing

Electrical EMC and safety testing were conducted on the SK MED Ophthalmic Ultrasound SK-3000A with the following standard:

ANSI AAMI 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;

ANSI AAMI ES 60601- 1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/ (R) 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601- 1:2005, MOD);

IEC 60601-2-37: 2007 + AMD1:2015 Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

Acoustic output testing

According to the "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" FDA Guidance document, issued on July 27, 2019, the test methodology and set-up follow Track 1 recommendations for diagnostic ultrasound systems and transducers.

Clinical testing

Not applicable.

Software Verification and Validation

The software and cybersecurity have passed verification and validation program. And the results comply with the requirements.

In all tests these devices are in compliance with above FDA recognized standards, therefore these devices are safe and effective.

Conclusions

Based on the technical characteristics and the results of the performance tests, we conclude that Sunkingdom Ophthalmic Ultrasound Examination Instrument SK-3000A, SK-3000B, SK-3000C, SK-2000AP, SK-2000A, SK-2000P are substantially equivalent and as safe and effective as the main predicate device MEDA Ultrasonic A/B Scanner (K063433) .