December 19, 2019

Chongqing Sunkingdom Medical Instrument Co., Ltd
Shulin Guo
1012, Block A of China Resource Center No.55 of XieJiaWan
JiuLongPo
Chongqing, 400050 Cn

Re: K191314
Trade/Device Name: Sunkingdom Applanation Tonometer SK-R, SK-T, SK-Q
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer And Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: October 20, 2019
Received: November 25, 2019

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,

for Elvin Ng
Acting Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191314

Device Name
Sunkingdom Applanation Tonometer SK-R, SK-T, SK-Q

Indications for Use *(Describe)*
Sunkingdom Applanation Tonometer is a manual device intended for measurement of intraocular pressure by applanation (applying a small flat disk to the cornea) to aid in the diagnosis of glaucoma.

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

This summary of 510k safety and effectiveness is being submitted in according with 21 CFR part 807.92

Chongqing Sunkingdom Medical Instrument Co., Ltd
35-2, YingTianGuanTianGongGu, CaiJiaGang Industry Zone, BeiBei District, ChongQing, China
Contact Person: Shulin Guo
Phone: +86 2368677919
Fax: +86 2368102793
E-mail: 13346822@qq.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: December 18, 2019

Proprietary Name: Sunkingdom ApplanationTonometer
SK-R, SK-T, SK-Q

Common or Usual Name: Manual Tonometer

Classification Name: Tonometer and Accessories
21C.F.R. 886.1930
Class II

Productcode: HKY

Review Panel: Ophthalmic

Predicate Devices

Predicate devices	Digital Keeler Applanation Tonometer
Manufacturer	Keeler Ltd
K#	K142179 &K133234

Intended Use/ Indication for Use

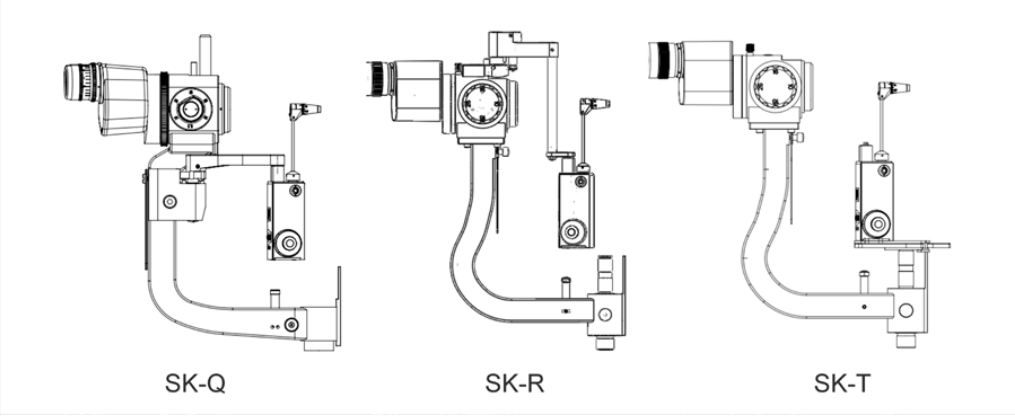
Sunkingdom Applanation Tonometer is a manual device intended for measurement of intraocular pressure by applanation (applying a small flat disk to the cornea), to aid the diagnosis of glaucoma.

Device Description

Sunkingdom SK-R, SJ-T, SK-Q are applanation tonometers, which are indicated for measurement of intraocular pressure (IOP). Intraocular pressure (IOP) is a very important physiological parameter and has always been an indispensable part of the diagnosis and treatment of ophthalmology, especially for glaucoma.

The operation principle is based on Goldmann applanation method, which is considered as the gold standard for measuring intraocular pressure. Therefore the applanation tonometer plays an important role in the diagnosis and treatment of ophthalmic diseases.

Sunkingdom series of Applanation tonometer are active medical devices powered by 3V button battery. In practice, it provides two ways to read the measured intraocular pressure value, one from the dial indicator in mmHg unit, the other from the LCD display in mmHg and KPa units. It is used in conjunction with a slit lamp, and the only difference among the SK- R, SK-T, SK-Q is the connection part. Each model differs from each other depending on the type of slit lamp to be used with it as shown in the figure below. All the other technical specifications are the same for these three models.



Model SK-Q is especially for the slit lamp with a large head size that cannot be configured for SK-R. Model SK-R can be left on the slit lamp permanently. It is fixed to the microscope on a mounting base and can be rotated in front of the microscope for examination. Model SK-T is mounted on the guide plate over the slit lamp axis for measurement purposes.

Components of the tonometer include applanation tonometer main body, Connection mechanical parts and screws, calibration rod, and applanation prism.

Principle of Operation

Applanation Tonometer is an appliance that serves to measure intraocular pressure according to the Goldmann method, also known as Goldmann Applanation Tonometer(GAT). The intraocular pressure, measured by applanation tonometer, is calculated from the force required to flatten a constant area of the cornea according to the principle of the Immant-Fick of the Goldmann applanation tonometer: Pt (intraocular pressure) = W (external force of the flattened cornea) / A (flattened area).

Method of Operation

A sterile disposable measurement prism is mounted on the tonometer head at the end of the measurement arm and placed against the cornea after the cornea has been anaesthetized. Set the illumination light of the slit lamp to be cobalt blue and the angle between illumination arm and microscope to be in the range of 40-60 degrees.

By moving the slit lamp, the measuring prism comes into contact with the centre of the cornea over the pupillary area. The examiner then uses the cobalt blue filter to view the semi circle in view, then adjust the measurement drum on applanation tonometer to apply force to the tonometer head until the inner edges of the semi circle in the view meet, then read the display value on the screen or on dial indicator.

Calibration

During factory calibration procedure, known pressures covering the measurement range are applied to the measurement arm using a calibration arm according to the calibration procedure outlined in the Tonometer standard ISO 8612:2009.

The calibration procedure establishes a relationship between the pressure applied to the measurement arm and the position of the measurement drum. Linear interpolation is used between calibration points.

Substantial Equivalence

The Sunkingdom SK-R, SK-T, SK-Q are considered to be substantially equivalent to the predicate device Keeler Ltd Digital Keeler Applanation Tonometer (K142179 &K133234) as the Sunkingdom applanation tonometer SK-R, SK-T, SK-Q have the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicates.

Comparison of the predicate device

Descriptive information	**Predicate Device**	**Proposed Device**	**Description of differences and discussion**
Manufacturer	Keeler Ltd	Chongqing Sunkingdom Medical Instrument Co.,Ltd	
510(k)Number	K142179 & K133234	K191314	
Proprietary or Model Name	Digital Keeler Applanation Tonometer (D- KAT)	Sunkingdom Applanation Tonometer SK-R, SK-T, SK-Q	
Type	Manual contact Tonometer	Manual contact Tonometer	No change
Indications for Use	Indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.	Indicated for measuring intraocular pressure to aid in the screening and diagnosis of Glaucoma.	No change
Indicated use	Intraocular Pressure (IOP) measurement	Intraocular Pressure (IOP) measurement	No change
Target population	Patients with high IOP	Patients with high IOP	No change
Anatomical sites	Cornea	Cornea	No change
Units of measure	mmHg - millimetre of mercury	mmHg - millimetre of mercury &Kpa-Kilo pascal	In the LCD displayer, Sunkingdom Applanation tonometer has an additional Kpa unit. The internal equation of two units as follow: 1mmHg=0.1333224KPa. It takes the doctor's habits into account and provides better practical applications for use. The change does not affect the intended use, safety and effectiveness or the fundamental scientific technology.
Display	Numerical display - Direct reading of IOP in mmHg from display	Numerical display - Direct reading of IOP in mmHg and Kpa from display	

Descriptive information	Predicate Device	Proposed Device	Description of differences and discussion
Design	Mounted on top illuminating (Haag Streit-style) and bottom illuminating (Zeiss style) Slit lamp, manual dial	Mounted on top illuminating (Haag Streit-style) and bottom illuminating (Zeiss style) Slitlamp, manual dial	No change
Where Used	In a professional healthcare facility environment	In a professional healthcare facility environment	No change
Measurement Range	5-65mmHg	0-80mmHg	Sunkingdom Applanation tonometer has a wider measurement range than that of Keeler's. It takes professional's practice requirement into account and provides better practical applications for use. The change does not affect the intended use, safety and effectiveness or the fundamental scientific technology.
Measurement technique	Applanation	Applanation	No change
Measurement Method	Goldmann method - the measuring of pressure to maintain a uniform applanation of the surface of the eye.	Goldmann method - the measuring of pressure to maintain a uniform applanation of the surface of the eye.	No change
Measurement deviation	0.49 mN or 1.5% of measurement value, whichever is the greater	0.49 mN or 1.5% of measurement value, whichever is the greater	No change
Power requirements	AA battery to power digital display	3V button battery to power digital display	Sunkingdom Applanation tonometer's battery is smaller than that of Keeler's in volume. It just for battery space consideration nothing about battery capacity. The change does not affect the intended use, safety and effectiveness or the fundamental scientific technology.

Descriptive information	**Predicate Device**	**Proposed Device**	**Description of differences and discussion**
Software	Contains software	Contains software	No change
Mounting method on slit lamp	Fixed (R-Type) and Take-away (T-Type)	Fixed (R-Type, Q-Type) and Take-away (T-Type)	No change
Maintenance and Calibration	Maintenance and calibration required factory set calibration arm assembly is supplied with each device to check calibration	Maintenance and calibration required factory set calibration arm assembly is supplied with each device to check calibration	No change
Materials	Tonometer body-anodized aluminium; Tonometer prism-Medical grade acrylic	Tonometer body-anodize aluminium; Tonometer prism-Medic grade acrylic	No change
Biocompatibilit y	All materials are tested for biocompatibility	All materials are tested for biocompatibility	No change

Performance Data

The following performance data were provided to support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the patient contact material (measuring prism) of Sunkingdom Applanation tonometer was conducted accordance with the 21 CFR 58 Good Laboratory Practice for Nonclinical Laboratory Studies,

ISO 10993-1:2009 “Biological evaluation of Medical Devices Part .1 –Evaluation and testing within a risk management process”

ISO 10993-10:2010 “Biological Evaluation of Medical Devices-Part 10: Tests For Irritation And Skin Sensitization”, Jul, 26, 2016

ISO 10993-12:2012 “Biological evaluation of Medical devices Part.12 – Sample preparations and reference materials”

ISO 10993-5:2009 “Biological Evaluation of Medical Devices-Part 5: Tests For In Vitro Cytotoxicity”, Dec, 23, 2016,

ISO 10993-11:2009 “Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity”

as recognized by FDA.

The Applanation tonometer prism of testing included the following tests:

Vitro Cytotoxicity
Irritation
Skin Sensitization
Systemictoxicity

The extract of applied sample obtained from MVLV48 LENTILLE is not cytotoxic in accordance with ISO 10993-5:2009 “Biological Evaluation of Medical Devices- Part 5: Tests for In Vitro Cytotoxicity”.

The polar and non-polar extracts of the test item MVLV48 LENTILLE do not have to be classified as a skin sensitizer, in accordance with ISO 10993-10:2010 “Biological Evaluation of Medical Devices-Part 10:Tests For Irritation And Skin Sensitization”. It also meets the requirement of ISO 10993-11:2006 and ISO 10993- 10:2010.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Sunkingdom Applanation Tonometer SK-R, SK-T, SK-Q. The system complies with the following standard:

ANSI AAMI IEC60601-1-2:2014, standard for EMC,

ANSI AAMIES 60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R) 2012 and A2:2010/ (R) 2012Jul, 09, 2014, standard for safety,

ISO 15004-1:2006 Ophthalmic instruments -- Fundamental requirements and test methods -- Part 1: General requirements applicable to all ophthalmic instruments.

Performance Testing

Verification bench testing has been carried out in accordance to the FDA guidance Tonometers-Premarket Notification [510(k)] Submissions. Bench testing using a balance system was carried to verify the measuring force, and conducted by an experimenter to measured each weight value for 10 times and by 2 experimenter to measured 3 weight values for 2 times in 3 devices. The testing was carried out in accordance with ANSI Z80.10-2014, Ophthalmic Instruments-Tonometer.

In all tests these devices are in compliance with above FDA recognized standards.

Conclusions

In accordance to 21 CFR 807.92(d) and based on the technical characteristics and the results of the performance tests we conclude that Sunkingdom Applanation Tonometers SK-R, SK-T, SK-Q are substantially equivalent and as safe and effective as the predicate device Digital Keeler Applanation Tonometer (D-KAT) from Keeler Ltd (K142179 &K133234).