DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 17, 2017

Takagi Seiko Co., Ltd.
Shinya Kitamura
Official Correspondent Legal & Regulatory Affairs
330-2 Iwafune
Nakano-shi, Nagano-ken 383-8585 JP

Re: K172728
Trade/Device Name: Applanation tonometer AT-1
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer and Accessories
Regulatory Class: Class II
Product Code: HKY
Dated: September 5, 2017
Received: September 11, 2017

Dear Shinya Kitamura:

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 yours,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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)*
K 172728

Device Name
Applanation Tonometer AT-1

Indications for Use *(Describe)*
The Applanation Tonometer AT-1 is indicated to measure intraocular pressure for use as an aid in glaucoma screening and diagnosis.

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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K172728

510(k) Summary

1. SUBMITTER

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Date Prepared:	October 12, 2017

2. DEVICE

Name of Device:	Applanation Tonometer AT-1
Models:	Arm Model, Base Model
Common Name:	Goldmann Tonometer
Classification Name:	Tonometer and Accessories (21 CFR 886.1930)
Regulatory Class:	II
Product Code:	HKY

3. PREDICATE DEVICE

Manufacturer:	HAAG - STREIT
Device trade name:	APPLANATION TONOMETER AT 900
Regulatory Class:	II
Product Code:	HKY
510(k) number:	K981432

This predicate has not been subject to a design-related recall.

(1) No records were found with Product: applanation tonometer AT 900 Date Classified from: 1980 Date Classified to: 2015 (https/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm)

4. DEVICE DESCRIPTION

4.1 Device Identification

The device consists of a pressurizing force control unit, tonometer tip (hereinafter referred to as measuring prism), section connected to a slit lamp microscope, and accessories. The measuring prism requires disinfection. The device is available in two models according to the difference in the method of connecting to a slit lamp microscope, while the pressurizing force control unit and measuring prism are the same for the two models. Each model includes no electrical elements. The device is set up to a dedicated support on the slit lamp, and used together with a commercially available slit lamp microscope. The pressurizing force control unit of the device incorporates a measurement dial that indicates pressurizing force, including a pressurizing force control knob, and a prism holder to mount the measuring prism. Also, the pressurizing force control unit includes a connector for mounting a check weight holder to check the pressurizing force of the device. The product is a manual medical device.

4.2 Related accessories are as follows:

Check weight / check weight holder used to check the pressurizing force of the device

4.3 Models are as follows:

1) Arm Model

The arm model can be left on a slit lamp permanently as it is fixed to the mounting base of the microscope of the slit lamp, and it is turned in front of the microscope for examination. The applanation surface is observed monocularly through the left eyepiece lens.

2) Base Model

The base model is set on the slit lamp shaft by the guide plate, and it can be moved between two positions on the guide plate for observation through the right or left eyepiece lens.

4.4 Device Characteristics

1) Patients-contacting material: PMMA.

2) The measuring prism of the device is reusable.

3) Cleaning and disinfection method

The cleaning and disinfection method of the measuring prism of the device is as follows:

a) Manual washing.

b) Immersion in disinfectant.

c) Manual removal of disinfectant with running.

4.5 Environment of Use

4.5.1 Areas of application of the device

The Applanation Tonometer AT-1 is intended for use in medical offices, hospitals, and in optometrist and optician offices and clinics.

4.5.2 Ambient conditions

Temperature: +10℃ to +35℃

Air Pressure: 800hPa to 1060hPa

Relative humidity: 30% to 75%

4.6 Method of Operation

In applanation tonometry the intraocular pressure is calculated from the force required to flatten a constant area of the cornea.
The operation principal based on Goldmann applanation method.

4.7 Materials of Use

General type of material used

The Applanation Tonometer AT-1 comes into contact with patients' corneal mucosal membrane surface, the material is acrylic resin and the contact time is limited exposure, respectively.

Other component parts of the device are made of general materials (example: stainless Steel, copper alloy, and aluminum alloy).

4.8 Calibration

Pressure applied to the pressurizing arm is periodically checked by use of the check weight during factory production/by users.

5. INDICATIONS FOR USE

The Applanation Tonometer AT-1 is indicated to measure intraocular pressure for use as an aid in glaucoma screening and diagnosis.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

6.1 Comparison of AT900 and AT-1

Table 1. Applanation Tonometer AT-1 (Arm Model & Base Model) vs. HAAG-STREIT Applanation Tonometer AT900

Comparison of Goldmann Tonometer Technical Characteristics Applanation Tonometer AT-1 vs. Haag-Streit AT900			
Criteria	Predicate Device Haag-Streit AT900		New Device Applanation Tonometer AT-1
510(k) Number	K981432		K172728
Type	Manual contact Tonometer		Manual contact Tonometer
Indication	Intraocular Pressure (IOP) measurement		Intraocular Pressure (IOP) measurement
Design	Slit lamp mounted Manual dial		Slit lamp mounted Manual dial
Prism Material	PMMA		PMMA
Measurement Range	0 – 80mmHg		0 – 80mmHg
Measurement Method	Applanation		Applanation

Measurement technique	Direct reading of IOP in mmHg (each division on dial of measuring drum is equal to 0.2gf (1.96mN))		Direct reading of IOP in mmHg (each division on dial of measuring drum is equal to 0.2gf (1.96mN))
Applanation circle diameter	3.06mm		3.06mm
Calibration	Maintenance and calibration required		Maintenance and calibration required
Intended use	The goldmann manual tonometer is an appliance that serves to measure intraocular pressure, according to the goldmann method. The measuring of the pressure requires to maintain a uniform applanation of the surface of the cornea. It is specially indicated in glaucoma disease.		The Applanation Tonometer AT-1 is indicated to measure intraocular pressure for use as an aid in glaucoma screening and diagnosis.

6.2 Technical Specifications

Table 2. Applanation Tonometer AT-1 (Arm Model & Base Model) vs. HAAG-STREIT Applanation Tonometer AT900

Item \ Models	Predicate Device Haag-Streit AT900	New Device Applanation Tonometer AT-1	
		Arm Model	Base Model
Measurement range	0-80mmHg		
One scale unit	1.96mN		
Measurement accuracy	±1.5 % of the nominal value or ±0.49 mN, whichever is greater		
Repeatability	≦0.50mN		
Reverse span	0.49mN		
Applanation circle diameter	3.06mm ± 0.02mm		
Applanation area	7.354 ㎟		
Dimensions (millimeter)	89(W)×115(D)×250(H)	71.2 (W)x135.0(D)x249(H)	71.2(W)x80(D)x184(H)
Weight	0.5kg	0.44kg	0.34kg

7. PERFORMANCE AND SAFETY

7.1 Performance Testing

Performance of the Applanation Tonometer AT-1 was tested in accordance with ISO 8612:2009-Ophtalmic Instrument-Tonometers, Annex A.2.

7.2 Validation of Cleaning and disinfection Methods

Regarding the reusable measuring prism, validation of the cleaning and disinfection method is carried out by the validation test, and it is confirmed that it passed.

7.3 Life

Shelf life and service life of Applanation Tonometer AT-1 and the measuring prism are described.

7.4 Material Biocompatibility

Concerning the safety of Applanation Tonometer AT-1 material which comes in direct contact with a patient's eyes, comparative evaluations were performed with the Predicate Device by applying ISO 10993-1:2009-Biological evaluation of medical device-Part 1: Evaluation and testing within a risk management process.

7.5 Labeling

For usage methods and cleaning and disinfection methods of the Applanation Tonometer AT-1, an instruction manual is provided.

8. Conclusion

According to each evaluation result as mentioned above, the Applanation Tonometer AT-1 is substantially equivalent to the predicate device in safety, performance, specifications and etc.