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

April 14, 2017

Takagi Seiko Co., Ltd.
Hagiwara Toru
Official Correspondent
330-2 Iwafune, Nakano-Shi, Nagano-Ken
Nakano, 383-8585 JP

Re: K162636
Trade/Device Name: Marco Ultra M3, Marco Ultra M4
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: March 2, 2017
Received: March 7, 2017

Dear Hagiwara Toru:

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,

Bradley S. Cunningham -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162636

Device Name
Marco Ultra M3, Marco Ultra M4

Indications for Use *(Describe)*
An AC-powered slit-lamp biomicroscope and accessories intended for use in the examination of the anterior eye segment, from the cornea epithelium to the posterior capsule.
It is used to aid in the diagnosis of diseases or traumas which affect the structural properties of the anterior eye segment.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TAKAGI SEIKO CO.,LTD.
330-2 IWAFUNE, NAKANO-SHI, NAGANO-KEN, 383-8585, JAPAN
TEL. +81-269-22-4512 FAX. +81-269-26-6321
URL: http://www.takagi-j.com E-mail: info@takagi-j.com

510(k) Summary

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

1. Submitter of this pre-market notification:

TAKAGI SEIKO CO., LTD.
330-2 Iwafune, Nakano-shi, Nagano-ken,
Japan 383-8585

Contact Person:
Toru Hagiwara
Phone: +80-269-22-4511
Fax : +81-269-26-6321
Email: hagiwara.Toru@takagi-j.com

Date prepared: This summary was prepared on April 10, 2017

2.Trade names of the devices:

MARCO ULTRA M3
MARCO ULTRA M4

3.Common / Usual name:

AC-Powered Slit-lamp Biomicroscope

4.Classification Information:

Classification name:	Biomicroscope, Slit-Lamp, AC-Powered
CFR title:	21 CFR 886.1850
Product code:	HJO
Device Class:	Class II
Classification Panel:	Ophthalmic Panel

5. Predicate Devices:

We claim substantial equivalence to the following devices

Manufacture:	Haag-Streit AG
Device name:	Slit Lamp BM900
510(k) Premarket Notification No:	K100202
Classification name:	Biomicroscope, Slit-Lamp, AC-Powered
CFR title:	21 CFR 886.1850
Product code:	HJO
Device Class:	Class II
Classification Panel:	Ophthalmic Panel

Manufacture:	TAKAGI SEIKO CO., LTD
Device name:	Z2 Slit lamp microscope
510(k) Premarket Notification No:	K152535
Classification name:	Biomicroscope, Slit-Lamp, AC-Powered
CFR title:	21 CFR 886.1850
Product code:	HJO
Device Class:	Class II
Classification Panel:	Ophthalmic Panel

6. General Device Description:

An AC-powered slit lamp biomicroscope is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

An AC-Powered slit lamp biomicroscope is an AC-powered device that is a microscope intended for use in eye examination that projects into a patient's eye through a control diaphragm a thin, intense beam of light.

The slit lamp illumination is composed of the light source, the slit, collimation and imaging optics, and infrared and ultra violet filters and a dielectric mirror. The slit lamp have the option to combine a background illumination together with the slit illumination.

The patient sits in front of the slit lamp with his chin in the chin rest and his forehead against the forehead band. The chin rest is adjusted in height until the eyes of the patient are level with the black mark of the headrest column. The light is switched on and the brightness is controlled with a knob on the power supply. With the joystick control lever the instrument can be moved back and forward until the slit appears in focus on the cornea. The image can be observed through the microscope. Various magnifications can be selected on the microscope. For different observations the slit width can be changed, the slit can be tilted horizontally and vertically, and the angle between the illumination unit and the microscope can also be varied horizontally.

7. Indication for use:

An AC-powered slit-lamp biomicroscope and accessories intended for use in the examination of the anterior eye segment, from the cornea epithelium to the posteriorcapsule. It is used to aid in the diagnosis of diseases or traumas which affect the structural properties of the anterior eye segment.

8. Comparison with predicate devices:

The MARCO ULTRA M3 is substantially equivalent to the predicate device Slit Lamp BM900 because they use similar technology and perform similar functions to provide the physician with the necessary information to aid in diagnosis.

The MARCO ULTRA M4 is substantially equivalent to the predicate device Z2 Slit lamp microscope because they use similar technology and perform similar functions to provide the physician with the necessary information to aid in diagnosis.

Major different technological characteristics are as follows:

	Predicate Device Slit lamps Slit Lamp BM900((K100202) Z2 Slit lamp microscope(K152535)	TAKAGI Slit lamps MARCO ULTRA M3(K162636) MARCO ULTRA M4(K162636)
Brightness Controls	For BM900 (K100202) Variable control by potentiometer Maximum brightness approx. 450'000 Lux For Z2(K152535) Control by Light intensity control knob Maximum brightness approx. 150'000 Lux	For ULTRA M3(K162636) Control by Light intensity control knob Maximum brightness approx. 240'000 Lux For ULTRA M4(K162636) Control by Light intensity control knob Maximum brightness approx. 150'000 Lux
Slit image width	For BM 900(K100202) 0-8mm continuous For Z2(K152535) 0-14mm	For all Slit lamps(K162636) 0-14mm continuous
Slit image length	For BM 900 (K100202) 1-8mm continuous For Z2(K152535) 1-14mm continuous	For all Slit lamps(K162636) 1-14mm continuous

	Predicate Device Slit lamps Slit Lamp BM900 (K100202) Z2 Slit lamp microscope(K152535)	TAKAGI Slit lamp MARCO ULTRA M3(K162636) MARCO ULTRA M4(K162636)
Illumination field Diameter	For BM900(K100202) φ8,φ5,φ3,φ2,φ1,φ0.2 mm For Z2(K152535) φ14,φ8,φ5, φ3,φ0.3 mm	For M3(K162636) φ10,φ5, φ3, φ2, φ1, φ0.2 mm For M4(K162636) φ14,φ8,φ5, φ3,φ0.3 mm
Radial movement of the slit light illumination relative to the microscope axis	For BM900(K100202) Horizontal ±90° Vertical 0 - 20° For Z2(K152535) Horizontal±90° Vertical don't apply	For M3(K162636) Horizontal±90° Vertical 0°,5°,10°,15°,20° For M4(K162636) Horizontal±90° Vertical don't apply
Light source	For BM900(K100202) and Z2(K152535) LED	For all Slit lamps(K162636) LED
Background illumination	For BM900(K100202) Option For Z2(K152535) None	For M3(K162636) None For M4(K162636) Mounted in Slit lamp unit

9. Performance, safety and EMC Data:

The slit lamps M3 and M4 were tested according to ISO 15004-2:2007 and ISO10939:2007 for radiation hazards, to IEC60601-1 for electrical safety and IEC-60601-1-2 for electromagnetic compatibility. In all tests, the slit lamps were in compliance with these FDA recognized standards.

10.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 the slit lamps M3 and M4 are safe and effective compared to the predicate device slit lamps BM 900 and Z2.