



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

May 26, 2016

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Takagi Seiko Co., Ltd.
Nagaike Yoshio
Official Correspondent
330-2 Iwafune, Nakano-shi,
Nagano-ken, 383-8585
JAPAN

Re: K152535

Trade/Device Name: Z5 Slit Lamp Microscope, Z2 Slit Lamp Microscope
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: April 18, 2016
Received: April 26, 2016

Dear Nagaike Yoshio:

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 yours,

 Kesia Alexander

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



Section 4: Indications for Use

510(k) Number (if known): None

Device Names : Z5 Slit lamp microscope
Z2 Slit lamp microscope

Indications 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 posterior capsule. It is used to aid in the diagnosis of diseases or traumas which affect the structural properties of the anterior eye segment.

Prescription Use X
(Part 21 CFR 801 subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)



Section 5: 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 June 17, 2015

2.Trade names of the devices:

Z5 Slit lamp microscope
Z2 Slit lamp microscope

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:	BQ900 Slit
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:	Topcon Medical Systems, Inc.
Device name:	SL-2G Slit lamp Microscope
510(k) Premarket Notification No:	K110489
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 affects 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 Z5 Slit lamp is substantially equivalent to the predicate device Slit Lamp BQ 900 because they use similar technology and perform similar functions to provide the physician with the necessary information to make diagnosis.

The Z2 Slit lamp is substantially equivalent to the predicate device Slit Lamp SL-2G because they use similar technology and perform similar functions to provide the physician with the necessary information to make diagnosis.

Major different technological characteristics are as follows:

	Predicate Device Slit lamps BQ 900 Slit lamp microscope SL-2G Slit Lamp microscope	TAKAGI Slit lamps Z5 Slit lamp microscope Z2 Slit lamp microscope
Brightness Controls	For BQ900 Variable control by potentiometer Maximum brightness approx. 450'000 Lux ForSL-2G Control by brightness control knob Maximum brightness Unknown.	For Z5 Control by Light intensity control knob Maximum brightness approx. 240'000 Lux For Z2 Control by Light intensity control knob Maximum brightness approx. 150'000 Lux
Slit image width	For BQ 900 0-8mm continuous ForSL-2G 0-14mm, can be adjusted gradually	For all Slit lamps 0-14mm continuous
Slit image length	For BQ900 1-8mm continuous ForSL-2G 1-14mm, can be adjusted gradually	For all Slit lamps 1-14mm continuous

	Predicate Device Slit lamps BQ 900 Slit lamp Microscope SL-2G Slit lamp Microscope	TAKAGI Slit lamp Z5 Slit lamp Microscope Z2 Slit lamp Microscope
Illumination field Diameter	For BQ900 Φ8,φ5,φ3,φ2,φ1,φ0.2 mm For SL-2G φ14,φ10,φ5, φ1,φ0.3 mm	For Z5 φ14,φ10,φ5, φ3,φ2,φ1,φ0.2 mm For Z2 φ14,φ8,φ5, φ3,φ0.3 mm
Radial movement of the slit light illumination relative to the microscope axis	For BQ900 Horizontal ±90° Vertical 0 - 20° For SL-2G Vertical to horizontal can be adjusted gradually	For Z5 Horizontal±90° Vertical 0° ,5° ,10° ,15° ,20° For Z2 Horizontal±90° Vertical don't apply
Light source	For BQ900 and SL-2G LED	For all Slit lamps LED

9. Performance, safety and EMC Data:

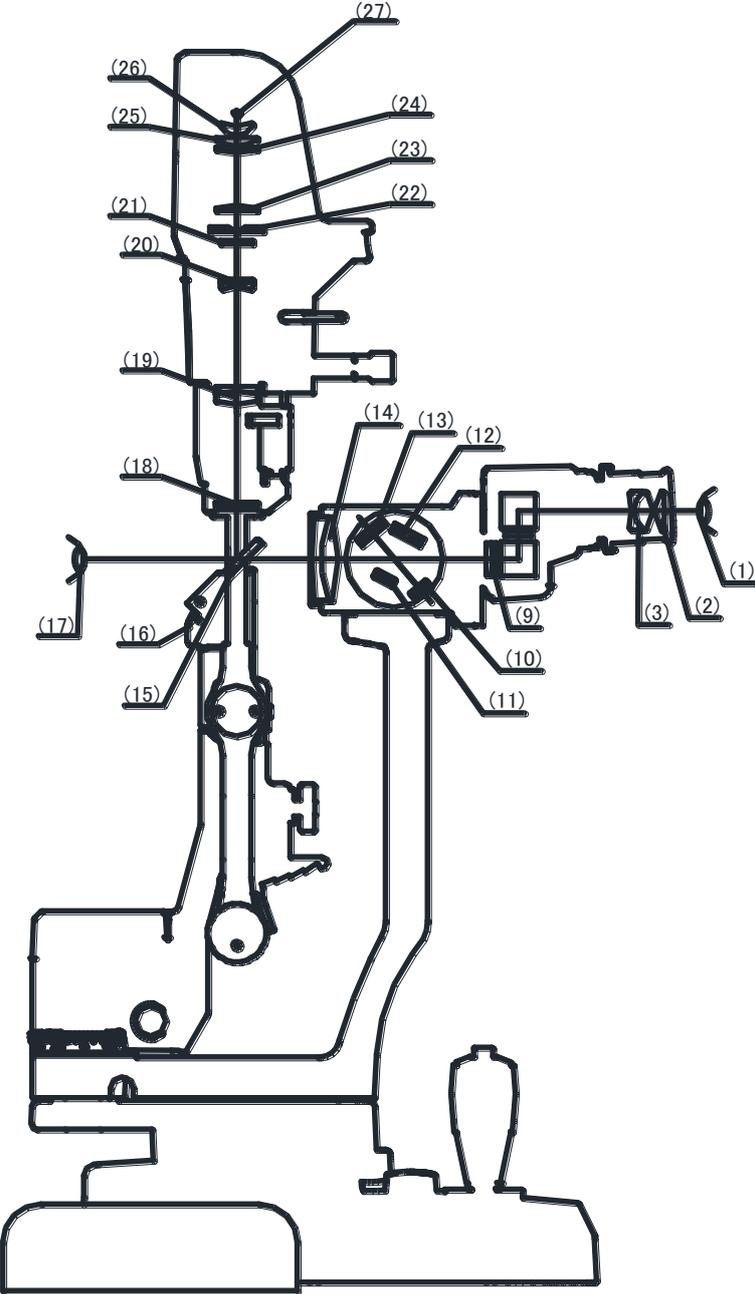
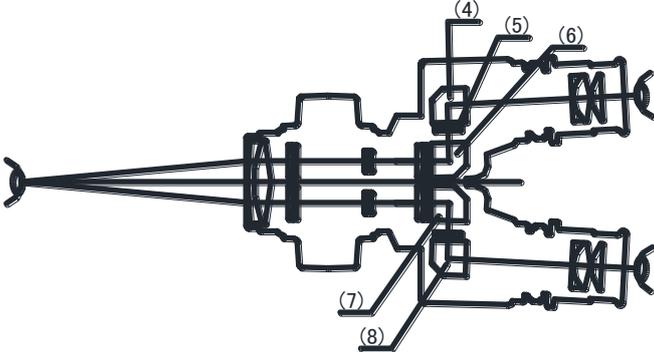
The slit lamps Z5 and Z2 were tested according to ISO 15004-2:2007 and ISO10939:2007 for radiation hazards, to IEC 60601-1 for electrical safety and IEC-60601-1-2 for electromagnetic compatibility. In all tests the slit lamps were in compliance with these FDA recognized standards.

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 Z5 and Z2 are safe and effective compared to the predicate device slit lamps BQ 900 and SL 2G.

11. Diagram of Optical Paths

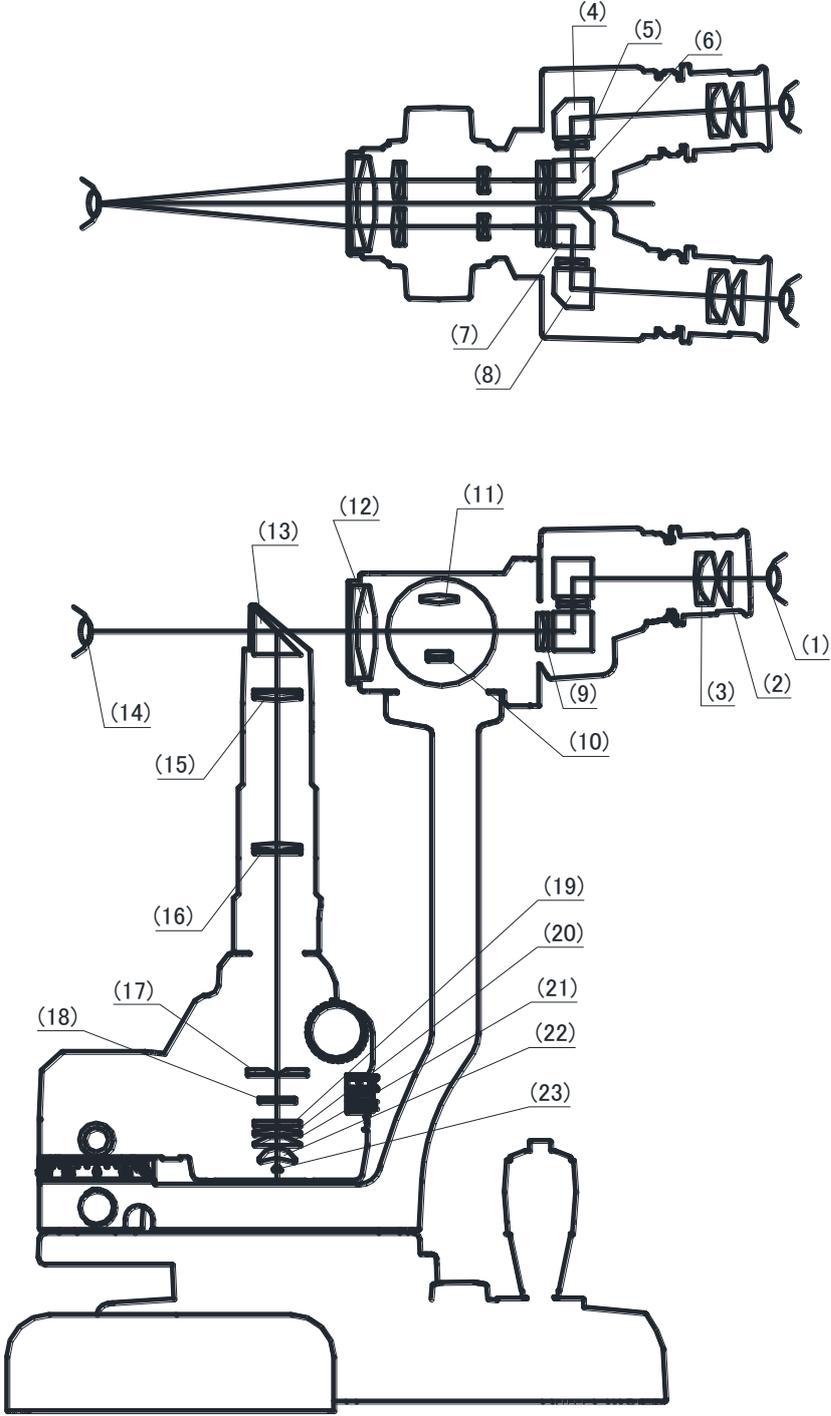
Z5 Diagram of Optical Paths



Z5 diagram parts name

(1) Examiner's eye	Eye of the user of this device
(2) Eyepiece lens	Optical element enlarging the observation image
(3) Eyepiece lens	
(4) Prism	Optical element changing the direction of light
(5) Lens	Light-gathering optical element
(6) Prism	Optical element changing the direction of light
(7) Prism	
(8) Prism	
(9) Lens	Light-gathering optical element
(10) Magnifying lens	Image zooming-in/out optical element
(11) Magnifying lens	
(12) Magnifying lens	
(13) Magnifying lens	
(14) Objective lens	Optical element taking in the light from the object under observation
(15) Mirror	Light-reflecting optical element
(16) LED light	Light source of background illumination
(17) Patient's eye	Eye of the person under observation
(18) Projection lens	Optical element projecting the slit image
(19) Projection lens	
(20) Projection lens	
(21) Filter	Optical element changing the wavelength of light
(22) Slit edge	Edge to make a slit image
(23) Condensing lens	Light-gathering optical element
(24) Condensing lens	
(25) Condensing lens	
(26) Condensing lens	
(27) LED light	Light source of slit illumination

Z2 Diagram of Optical Paths

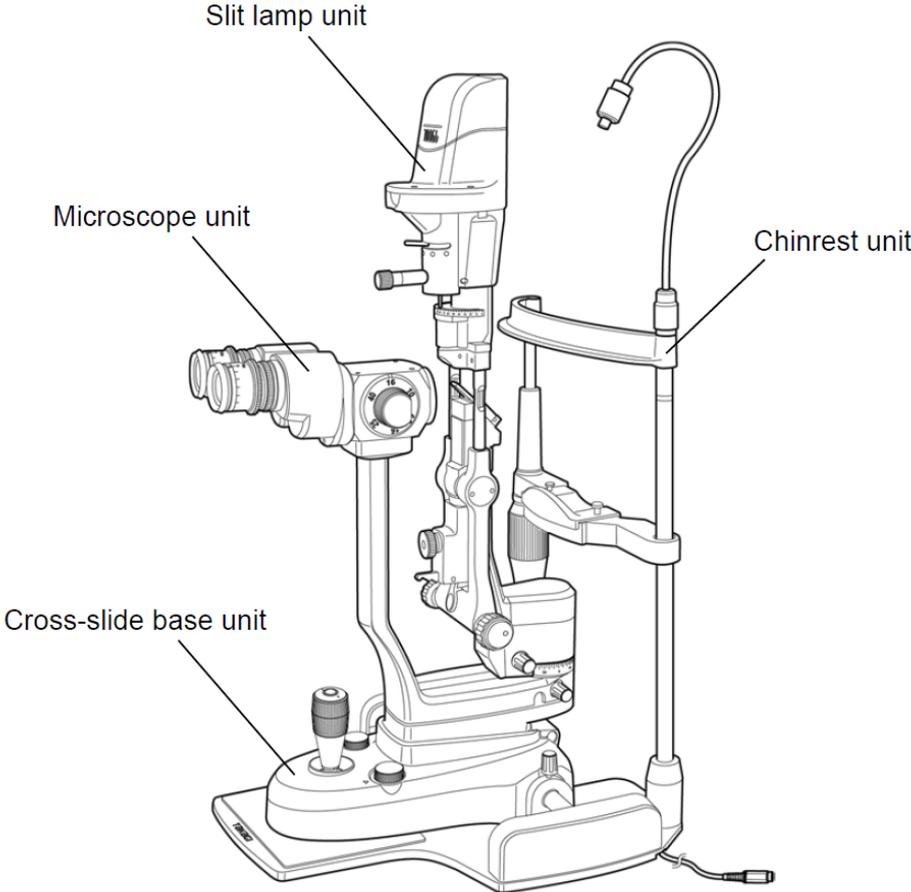


Z2 diagram parts name

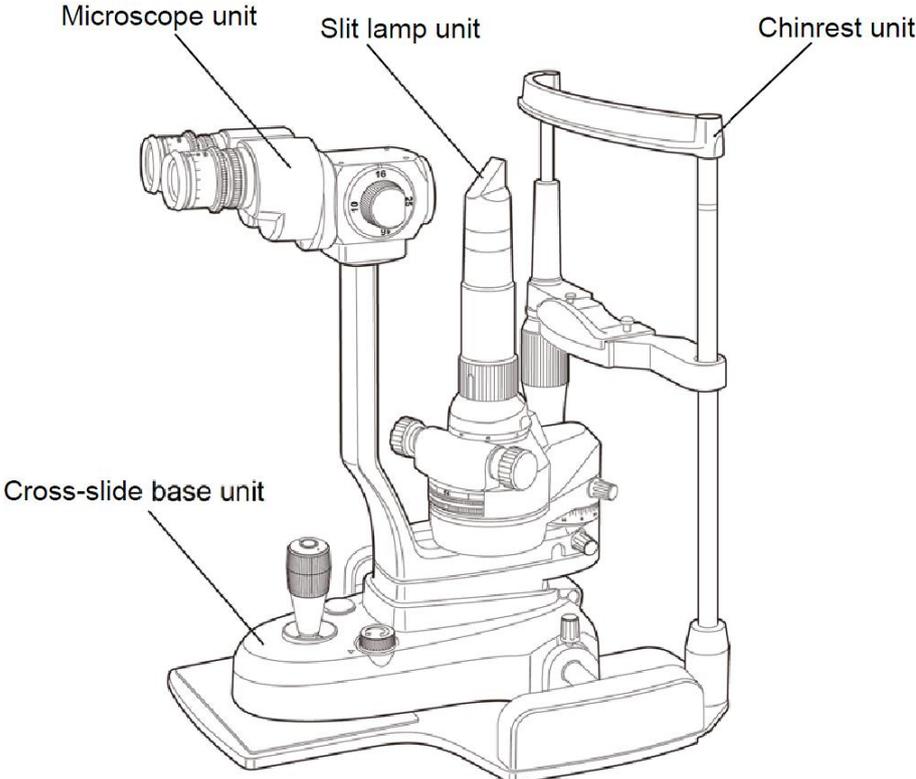
(1) Examiner's eye	Eye of the user of this device
(2) Eyepiece lens	Optical element enlarging the observation image
(3) Eyepiece lens	
(4) Prism	Optical element changing the direction of light
(5) Lens	Light-gathering optical element
(6) Prism	Optical element changing the direction of light
(7) Prism	
(8) Prism	
(9) Lens	Light-gathering optical element
(10) Magnifying lens	Image zooming-in/out optical element
(11) Magnifying lens	
(12) Objective lens	Optical element taking in the light from the object under observation
(13) Prism	Optical element changing the direction of light
(14) Patient's eye	Eye of the person under observation
(15) Projection lens	Optical element projecting the slit image
(16) Projection lens	
(17) Slit edge	Edge to make a slit image
(18) Filter	Optical element changing the wavelength of light
(19) Condensing lens	Light-gathering optical element
(20) Condensing lens	
(21) Condensing lens	
(22) Condensing lens	
(23) LED light	Light source of slit illumination

12. Differences between the Z5 and Z2

Z5



Z2

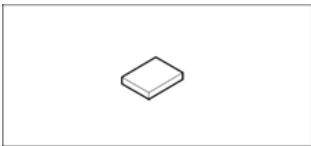
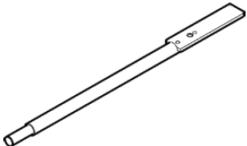


Major different technical

Performance

Comparing item	Z5	Z2
Slit projection magnification	0.98x	1x
Working distance	80mm	85mm
Brightness	φ0.2, φ1, φ2, φ3, φ5, φ10mm	φ0.3, φ1, φ3, φ5, φ8, φ14mm
Back ground illumination (Assistance light for taking photograph)	240,000lux	150,000lux
Tilting angle	Included in slit lamp unit Light adjustment knob is located on the cross - slide base unit.	No back ground illumination is equipped
Total magnifications	6.3x, 10x, 16x, 25x, 40x	10x, 16x, 25x
Real field of view	φ35.9, φ23.3, φ14, φ8.8, φ5.5mm	φ23.3, φ14, φ8.8mm
Fixation light (Guides the patient's line of sight and maintain it)	Standard parts	Optional parts
Weight	12.5kg	11kg

Accessories

Item name	Explanation	Z5	Z2
 <p>Short mirror (1 pc.)</p>	Prevent vignetting when used in tilting function	○	×
 <p>Focusing adjusting rod (1 pc.)</p>	Used in diopter confirmation	○	×
 <p>Focusing adjusting plate (1 pc.)</p>	Used in diopter confirmation	×	○