K123821

MAY 17 2013

Blue Focus

615Ricci Hall Sogang University, Shinsu-Dong Mapo-Gu Seoul, Korea 121-742

510K Summary

Applicant:

Blue Focus
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Date Prepared: May 17, 2013

Contact: Keith Han

Device Identification:

Trade name - **AIO HD Otoscope**
Common Name - Otoscope
Classification Name – otoscope (21 GFR 874.4770, Product Code ERA)

510 (k) Numbers and Product Codes of equivalent devices:

Dr.Camscope Video Otoscope: k031853 / Code: ERA 874.4770

Welch Allyn Video Otoscope: k943916 / Code: ERA 874.4770

Jed Med Instrument Video Otoscope: k904802 / Code: ERA 874.4770

Device Description

AIO camera system consists of the camera hand probe, main storage unit and otoscope tip.
The camera hand probe dimensions are 45 mm (w) x 60 mm (l) x 151 mm (h).

The main unit dimensions are 235 mm (w) x 225 mm (l) x 58 mm (h).
The otoscope tip is carefully inserted into the external ear to view the ear canal and ear drum.

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LED / Halogen Light comparison		
	Halogen Light (Dr.Camscope)	**LED (AIO HD Otoscope)**
a.Luminance measurements and light intensity	minimum illumination 2 lux	10 cm : 316.2 lux 15 cm : 160.2 lux 20 cm : 103.1 lux
b.Electrical specifications such as operating voltage	12v	12v
c.Temperature of device	49.9 C	27.6
d. Physical characteristics including dimensions	2mm lamp	Dimensions of **camera:** 45(w)x60(l)x151(h)mm, **Main unit:** 235(w)x225(l)x58(h)mm

The AIO HD scope and the Dr.Camscope have the same intended usage although they have different light sources. Both otoscopes fall under the same product code(ERA).

The following chart provides a comparison of the subject device and the predicate device, Dr. Camscope, listing relevant technological characteristics and other critical performance specifications, including:

a. Luminance measurements and light intensity

b. Electrical specifications such as operating voltage

c. Temperature of device

d. Physical characteristics, including dimensions.

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

May 17, 2013

Blue Focus Co. Ltd.
Mr. Keith Han
President
% Sometech Corporation
965 Oakland Rd
Suite 2B
Lawrenceville, Georgia 30044

Re: K123821
Trade/Device Name: AIO HD Otoscope
Regulation Number: 21 CFR 874.4770
Regulation Name: Otoscope
Regulatory Class: Class I
Product Code: ERA
Dated: April 1, 2013
Received: April 9, 2013

Dear Mr. Han:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Eric A. Mann -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

Indications for Use

510(k) Number (if known): __ K123821_____

Device Name: ____ **AIO HD Otoscope** _____

Indications for Use:

AIO HD otoscope is used to provide images of the ear canal and tympanic membrane. The AIO HD otoscope can be used to allow a physician a clear and focused view of the ear canal or tympanic membrane on a computer or monitor screen.

Prescription Use __x_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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