JUL 0 3 2014

5 510(k) Summary

5.1 General information

General information	
Manufacturer	**C.S.O. Srl** **Via degli Stagnacci 12/E** **50018 Badia a Settimo Scandicci (FI)** **ITALY**
Contact person	**Piet de Jong,** **+39 055 722 1958** **p.dejong@csoitalia.it**
Date Prepared	**16 July 2013**

5.2 Device information

Device information	
Trade name	**Cobra Fundus Camera**
Common Name	**Fundus Camera**
Classification Name	**Ophthalmic Camera, AC-Powered**
Regulation Number(s)	**21 CFR 886.1120** **21 CFR 892.2050**
Product Code(s)	**HKI, NFJ**
Panel	**Ophthalmic**

5.3 Predicate devices

The Cobra Fundus Camera is compared for substantial equivalence with Kowa nonmyd WX Ophthalmic Camera, manufactured by Kowa Company Ltd, Tokyo, Japan (K101628).

5.4 Device description

Cobra is intended for taking digital images of a human retina with or without the use of a mydriatic agent. A function for retinal plane capturing is provided. The instrument is furnished with an integrated 5MP CCD camera, and uses one (1) white LED for flashing, one (1) IR led for alignment and Infrared acquisitioning.

Cobra can be used with pupil diameters starting from 2.5 mm, and therefore can be used without the need for a mydriatic agent. Acquisition transfer is performed from the instrument to the accompanying PC via a Firewire cable.

5.5 Intended use

Cobra is an electromedical system that allows for digitally retrieving, acquiring and processing of a retinal image to the extent permitted by the laws and regulations for the exercise of their profession.

The instrument allows for a direct, 'live' monitoring on the computer screen, and capturing also in cases where the pupil diameter starts from 2.5 mm.

5.6 Substantial equivalence

In accordance with the predicate device standards tests have been executed, resulting in the same technological characteristics.

Cobra met all the requirements regarding to electrical safety (tests according to IEC 60601-1)

Cobra met all the requirements to ensure electromagnetic compatibility, according to IEC 60601-1-2.

Cobra met all the requirements of Group 1 instruments according to ISO 15004-2 in order to be in compliance to the standard.

Concerning software validity of the CSO software, an evaluation was made based on FDA guidance, *Guidance for the content of premarket submissions for software contained in medical devices*, was performed.

The validation of Cobra acquisition software is performed as a part of a system function test. All functions are tested and confirmed working with traceability of remaining anomalies in a tracking system. Two tests were performed, one on functional level and one on system unit level. Both tests have been verified as meeting test criteria. All functional tests have been passed, as well as unit level tests.

The level of concern of Cobra acquisition software is *moderate.*

To evaluate biocompatibility, biocompatibility assessment was performed. All materials used are the same as other legally marked devices in US.

Cobra was evaluated for risk management in accordance with ISO 14971:2012, and met all requirements of the standard. The risk management of the device was deemed satisfactory.

The hardware interface for image transfer is different from the predicate device, but it cannot be considered critical to the intended therapeutic, diagnostic, prosthetic or surgical use of the device, nor can it affect the safety and effectiveness of the device when used as labeled.

Remaining risks will be noted in the user manual, so users will be able to avoid them.

It is concluded that Cobra is substantially equivalent with regards to functionality, design verification and intended use, to the identified predicate device already in interstate commerce within the USA, and that any differences that do exist have no effect on the safety and effectiveness of the device

5.7 Performance test

Performance testing was conducted on the subject device and was found to perform as intended.

Cobra met all the requirements regarding to electrical safety (tests according to IEC 60601-1) and electromagnetic compatibility, according to IEC 60601-1-2.

Cobra met all the requirements of Group 1 instruments according to ISO 15004-2 in order to be in compliance to the standard.

Concerning software validity of the Cobra acquisition software, an evaluation was made based on FDA guidance, *Guidance for the content of premarket submissions for software contained in medical devices*, was performed.

To evaluate biocompatibility, biocompatibility assessment was performed. All materials used are the same as other legally marked devices in US.

Cobra was evaluated for risk management in accordance with ISO 14971:2012, and met all requirements of the standard. The risk management of the device was deemed satisfactory.

Remaining risks will be noted in the user manual, so users will be able to avoid them.

In conclusion we can say that Cobra is substantially equivalent to the predicate device since the same requirements to referenced standards regarding safety and effectiveness were met.

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

July 3, 2014

C.S.O. Srl.
c/o Mr. Claude Berthoin
Regulatory Consultant
Thema USA
110 East Granada Blvd., Suite 209
Ormond Beach, FL 32716

Re: K132987
Trade/Device Name: Cobra Fundus Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI, NFJ
Dated: May 28, 2014
Received: June 2, 2014

Dear Mr. Berthoin:

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" (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 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,

Kesia Y. Alexander -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)*
K132987

Device Name
CSO Cobra Fundus Camera

Indications for Use *(Describe)*
The CSO Cobra Fundus Camera is intended for taking digital images of a human retina with or without the use of mydriatic agent. The retinal image can be stored to an image filing device.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Leonid Livshitz -S
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