JUN 17 2014
K140450

Keeler
Ophthalmic Instruments

510(k) Summary of Safety and Effectiveness

1. Submitter's Information

The submitter of this special pre-market notification is:

Name:	Mr. Neil Atkins (Engineering Manager).
Address:	Keeler Limited, Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK
Company Phone No:	+44 (0) 1753 827125
Company Fax No:	+44 (0) 1753 827145
Contact Person:	Mr. Neil Atkins
Date summary prepared:	19th February, 2014
Date summary reviewed:	17th June, 2014

2. Device Identification

Device Trade Name:	Keeler Kapture Software
Common Name:	Ophthalmic Camera Accessory
Class:	II
Classification Panel:	86
Product Code:	HKI
Regulation Number:	886.1120

3. Predicate Device

K000368 Clement Clarke International Ltd EyeCap Imaging System

4. Device Description

The Keeler Kapture software is an ophthalmic imaging system. The Kapture software package is intended to run on a PC and will allow the user to capture images from a digital slit lamp or other camera for review and storage. Images can have basic adjustments (such as colour, brightness and contrast) and images can be visually compared.

5. Indications for Use

The Keeler Kapture Software is used by Health Professionals to capture, store and manage output images from Retinal Cameras, Fundus Cameras and Video Slit Lamps.

6. Summary of Technological Characteristics

Both the Keeler Kapture Software and the EyeCap Imaging System predicate device are software applications running under the Microsoft Windows Operating System on a Personal Computer. Both products have exactly the same technological characteristics in terms of network capability, workstations, camera interfaces and patient database.

7. Comparison with Cleared Device

The Keeler Kapture Software and the EyeCap Imaging System predicate device have exactly the same Indications for Use, technological characteristics and performance specifications.

8. Summary of Non-clinical Tests

A number of functional tests were carried out to verify the performance of the Keeler Kapture Software against the EyeCap Imaging System, a brief description of the tests is provided in the table below. All tests were passed.

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Kapture function/Feature	Present in EyeCap
Administration	
Allow log-in as administrator or user	Yes
Add and manage users and their scope	Yes
Add cameras and manage cameras	Yes
Assign cameras to workstations	Yes
Manage user configurable options	Yes
Manage user definable fields	Yes
Manage data entry formats	Yes
Manage system settings and file locations	Yes
Manage the database	Yes
Track changes to the database in an audit trail	Yes
Show statistical information about the system	Yes
Patient Database	
Allow addition, deletion and editing of patient data	Yes
Information and images collected from each patient visit shall be stored separately	Yes
Allow review of patient data and images	Yes
Allow searching of the database	Yes
Allow configuration of search reports	Yes
Image Capture	

Image capture shall be available from within a patient episode	Yes
It shall be possible to capture images from a camera	Yes
It shall be possible to adjust the brightness of images captured from a camera	Yes
It shall be possible to import an image from a file	Yes
When and image is captured, an "X" is assigned to indicate that there is no left or right eye assignment	Yes
It shall be possible to manually assign "L" or "R" to an image to indicate left or right eye	Yes
Image Adjustment	
It shall be possible to assign notes to an image	Yes
It shall be possible to alter how images are printed	Yes
It shall be possible to mosaic several images together	Yes
It shall be possible to split image planes by colour	Yes
It shall be possible to make annotations on the captured image	Yes
It shall be possible to present images together for comparison	Yes
Tools shall be provided to grade images	Yes
An image brightness map, or histogram shall be provided	Yes
It shall be possible to undo any image manipulation	Yes
It shall be possible to apply a time and date to captured images	Yes

9. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this Premarket Notification, Keeler Limited conclude that the Keeler Kapture Software is substantially equivalent to the predicate device.

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

June 17, 2014

Keeler Ophthalmic Instruments, Inc.
Mr. Eugene R. VanArsdale
Marketing Manager
456 Parkway
Broomall, PA 19008

Re: K140450
Trade/Device Name: Keeler Kapture Software (Versions: KAPTURE, KAPTURE Lite, KAPTURE Digital, KAPTURE View, and KAPTURE View+)
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI
Dated: May 8, 2014
Received: May 9, 2014

Dear Mr. Arnsdale:

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" (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 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 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)*
K140450

Device Name
Keeler Kapture Software Package (Versions: KAPTURE, KAPTURE Lite, KAPTURE Digital, KAPTURE View, and KAPTURE View+)

Indications for Use *(Describe)*
The Keeler Kapture Software Package is used by Health Professionals to capture, store and manage output images from Retinal Cameras, Fundus Cameras and Video Slit Lamps

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)*

Marsha L. Burke Nicholas -S

Digitally signed by Marsha L. Burke Nicholas -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300014022, cn=Marsha L. Burke Nicholas -S
Date: 2014.06.11 20:33:36 -04'00'

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