K121405

Welch Allyn

DEC 2 0 2012

510(k) Summary

[As described in 21 CFR 807.92]

Submitted by: Welch Allyn Inc.
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Date Prepared: December 11, 2012

Trade Name: Welch Allyn iExaminer

Common Name: iExaminer

Device Classification: Class II

Classification Reference: 886.1120, Ophthalmic Camera

Classification Product Code: HKI

Predicate Devices: Optomed Smartscope M5 EY3, Smartscope M5 ES1
Optomed Oy
510(k) K110986

KOWA Genesis-D
KOWA CO.LTD
510(k) K080681

EyeQuick
EyeQuick, LLC
510(k) K102412

Welch Allyn PanOptic #11800
Welch Allyn, Inc.
510(k) K003376

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Description of Device:

The Welch Allyn iExaminer is comprised of the adapter, the iPhone and the software application. The adapter is specifically designed to hold the iPhone 4 and iPhone 4S in a fixed position in order to align the camera in the iPhone with the optics of the Welch Allyn PanOptic.
The software application allows the user to capture, store, send, and retrieve images of the eye as seen through the PanOptic. With the Retinal image application, iExaminer Professional Version, the user has the ability to capture images of the patient's eye by activating the camera icon at the bottom of the iPhone tool bar. Additional icons, buttons and pages allow the user to save images, transfer images and retrieve previously saved images.

Indications for Use:

The iExaminer is an attachment and software used only with the iPhone 4 and iPhone 4S in conjunction with the Welch Allyn PanOptic Ophthalmoscope to allow users to capture, send, store and retrieve images of the eye. The device is intended to be used by trained personnel within a medical or school environment.

Technological Characteristics:

The PanOptic is not being changed. None of the technological characteristics and indications for use of the PanOptic are being changed.

The Welch Allyn iExaminer is composed of two components that are used in combination and in conjunction with the PanOptic. The adapter is a plastic bracket that aligns the optics of PanOptic with the camera of the iPhone 4 and iPhone 4S. The software that can be purchased along with the adapter allows the user to document images of the patient's eyes.
The software allows the user to capture images of the eye by using the Retinal Image button. Next the user can view these images and select the ones to save. The user can name the images for later retrieval. Also, if the iPhone is configured and the user is using the Professional version of the iExaminer software application they can print or email saved images.
The software Application itself has two versions, a Free version and a Professional version. The Free version only allows the user to save ten patient files and does not allow them print or Email the images. These are the only differences between the Free and Professional versions of the iExaminer software.

Non-Clinical Tests:

Verification and validation were conducted to ensure expected performance of the Welch Allyn iExaminer, compliance to applicable standards, and to demonstrate that it does not affect the functionality or performance of the PanOptic. The Welch Allyn iExaminer is an ophthalmic camera that allows the user to document images of the eye as seen through the PanOptic.

The following FDA Guidance and standards were applied to the modified device.

- ISO 14971 Application of Risk Management to Medical Devices
- Off the Shelf Software guidance.
- Guidance for the Content of Premarket Submission for software contained in Medical Devices.
- ISO 10940 2009 Ophthalmic instruments- Fundus cameras
- ISO 15004-1: 2006 Ophthalmic instruments-Fundamental requirements and test methods- Part 1: General requirements applicable to all ophthalmic instruments.
- ISO 15004-2 2:2007 Ophthalmic Instruments- Fundamental Requirements and Test Methods-Part 2: Light Hazard Protection
- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2 : 2007 Medical Electrical Equipment –Part 1-2 General Requirements for Safety – Collateral standard: Electromagnetic Compatibility.

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Device Comparison Tables

Overall Comparison.

The 510(k) consists of using the using the Welch Allyn iExaminer in conjunction with the PanOptic. The Welch Allyn iExaminer compares favorably to the predicate devices listed above in terms of technology, Intended use and Indications for use. The information in the tables below were obtained from 510(k) summaries found on the FDA database along with information obtained from the respective device websites.

Substantial Equivalence Discussion

The Welch Allyn iExaminer is substantially equivalent in intended use and technology. Like the predicate devices classified in product code HKI, the Welch Allyn iExaminer has a camera with the ability to digitally capture images of the eye along with the ability to store images on the device itself. Also, as with the predicates classified as HKI, the Welch Allyn iExaminer has the ability to electronically send/transfer these images to other Information Technology Equipment (e.g., personal computer). The Welch Allyn iExaminer transfers these images via email. The predicate devices transfer the images via a USB. As with the predicate devices, images on the Welch Allyn iExaminer can be retrieved for viewing at a later time.

As part of the clinical study, the electronic transfer of images by the Welch Allyn iExaminer and the subsequent downloading to a Personal computer were compared to the Optomed images that were electronically transferred and downloaded to the same personal computer. The transferred images were determined to be at least as accurate and adequate (carry sufficient imaging details) to discern important clinical information as the predicate Optomed device, and thus substantially equivalent.

The iPhone does not impart any energy into the eye as part of the iExaminer. The energy released into the eye by the Welch Allyn iExaminer is the same as the Welch Allyn PanOptic. The light source for the iExaminer is the Halogen bulb used by the PanOptic, i.e., no additional light source beyond the PanOptic's halogen bulb is utilized by the iExaminer. In addition, the Welch Allyn iExaminer has been tested and found to be in compliance to applicable industry standards.

Summary of Device Performance Confirmed by Bench Testing

Several bench tests were completed to confirm the device is substantially equivalent, based on standards, to the predicate device.

Summary of Device Performance Confirmed by Clinical Testing

As noted above, testing was conducted to confirm that the Welch Allyn iExaminer performed as intended to capture images that have sufficient detail to allow a trained professional to discern clinically important information.

Camera System Technical Specifications

Point of comparison	iPhone 4	iPhone 4S	Optomed Smartscope M5 EY3	EyeQuick EDOC-1000	KOWA Genesis D
Resolution	5.00 megapixel	8 megapixel	5.0 megapixel	Less than 1 megapixel	2 megapixel
Image type	JPEG	JPEG	JPEG	JPEG	JPEG / BMP
Focus type	Autofocus	Autofocus	Autofocus	Manual diopter	Information not available

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Point of comparison	iPhone 4	iPhone 4S	Optomed Smartscope M5 EY3	EyeQuick EDOC-1000	KOWA Genesis D
Image size / Resolution	2592 x 1936 (5.0MP)	3264 x 2448 (8.0MP)	2560 x 1920 (5.0 MP)	480 x 672 (< 1 MP)	2 megapixel
Sensor Type	CMOS	CMOS	CMOS	Information not available	CCD
Sensor Size	1/3.2	1/3.2	Information not available	Information not available	Information not available
Focal Length multiplier	7.62	8.20	Information not available	Information not available	Information not available
Aspect Ratio	16:9 / 4:3	16:9 / 4:3	Information not available	Information not available	Information not available
Lens focal length	29mm	35mm	Information not available	Information not available	Information not available
Zoom ratio	1.00x	1.00x	Information not available	Information not available	Information not available
Auto Focus	Yes	Yes	Yes	No	Information not available
Aperture Range	Fixed f/2.8	Fixed f/2.4	Information not available	Information not available	Information not available
ISO	Auto	Auto	Information not available	Information not available	Information not available
White Balance	Auto	Auto	Information not available	Auto	Information not available
Shutter Speed	1/15 – 1/10055	1/15 – 1/30000[2]	Information not available	Information not available	Information not available
First 3 categories reference Apple technical specs. http://www.apple.com/iphone/iphone-4/specs.html http://www.apple.com/iphone/specs.html The remaining categories reference www.imaging-resource.com, www.ephotozine.com.			Technical information was gathered from manufacturer product literature and labeling of devices	Technical information was gathered from manufacturer product literature and labeling of devices	Technical information was gathered from manufacturer product literature

Summary of Pupil diameter size, working distance and magnification.

Point of Comparison	**iExaminer**	**Optomed Smartscope M5 with EY3**	**EyeQuick – EDOC-1000**	**KOWA Genesis D**
Minimal Pupil Diameter Size	2 mm (Per PanOptic Ophthalmoscope)	3.5 mm	Information not available	8 mm recommended
Working Distance	25.4mm (Pupil to first optical surface on the objective lens. Per PanOptic Ophthalmoscope)	1 – 2 cm (from the surface of the eye)	5mm (between top of cornea and ophthalmoscope front)	5mm (between eye and prism)
Pixel Pitch (Per ISO 10940, Magnification of image is only applicable for fundus cameras recording on film. Pixel pitch is the applicable measurement for fundus cameras recording on a digital sensor)	Measured 5.37 um/pixel for iPhone 4 High res, 4.25 um/pixel for iPhone 4S High Res	Measured 8.77 um/pixel	Information not available	Information not available
Optical Magnification	1.183 (Per PanOptic Ophthalmoscope. Magnification: M=h'/h The Optical magnification (M) is defined by the ratio between the image size (h') and the object size (h). (h) = the object size of retinal detail (such as a blood vessel) (h') = the image size of the retinal detail (such as the image of that blood vessel))	Information not available	Information not available	Information not available

Summary of ISO 10940 performance (Predicate device comparison)

Criterion	Requirement		iPhone 4 Standard res	iPhone 4 High res	iPhone 4S Standard res	iPhone 4S High res	Optomed Smartscope M5 EY3
Resolving power on the fundus camera for fundus camera optics. Field of view ≤30°	Centre	≥ 80 lp/mm	82.94 lp/mm				Not possible to observe
	Middle (r/2)	≥ 60 lp/mm	74.12 lp/mm				Not possible to observe
	Periphery (r)	≥ 40 lp/mm	58.82 lp/mm				Not possible to observe
Tolerance of angular field of view	+/- 5%		-1.16 % (Measured 24.71° against 25° claim)	-1.16 % (Measured 24.71° against 25° claim)	-1.16 % (Measured 24.71° against 25° claim)	-1.16 % (Measured 24.71° against 25° claim)	+10.5% (Measured 44.23° against 40°claim by manufacturer)
Tolerance of magnification of image	N.A. (Fundus camera on a digital sensor)		NA	NA	NA	NA	NA
Tolerance of pixel pitch on fundus	+/- 7%		Measured 16.25 um/pixel	Measured 5.37 um/pixel	Measured 16.25 um/pixel	Measured 4.25 um/pixel	Measured 8.77 um/pixel
Range of diopter adjustment of the optical finder (when optical finder is attached)	-5D to +5D		-20D to +20D				At least -20D to +20D
Range of focus adjustment for compensation of patient's refractive error	-15D to +15D		-20D to +20D				At least -20D to +20D

Technical information was gathered from via engineering testing, manufacturer product literature, labeling of devices and by side-by-side comparison

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Device Comparison Table

Point of comparison	iExaminer (K121405)	Optomed Smartscope M5 with EY3(K110986)	KOWA Genesis-D (K080681)	EyeQuick EDOC-1000 (HKI, K102412)	Welch Allyn 11800 Ophthalmoscope (K003376)
Indications for use	The iExaminer is an attachment and software used only with the iPhone 4 and iPhone 4S in conjunction with the Welch Allyn PanOptic Ophthalmoscope to allow users to capture, send, store and retrieve images of the eye. The device is intended to be used by trained personnel within a medical or school environment.	Optomed Smartscope M5 camera with optics modules EY3 and ES1 is a digital ophthalmoscope intended to capture digital images and video of the fundus of the human eye and surrounding area.	To capture and save fundus images with mydriatic	The EyeQuick Digital Ophthalmoscope Camera is intended for use in capturing approximately 8 degrees narrow angle field of view images of the eyelids, retina and anterior segment of the eye.	The Welch Allyn model #11800 Ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous, and retina of the eye. It has the same operating principles and intended use as many competitive ophthalmoscopes already in commercial distribution. The device is intended to be used by trained personnel within a medical or school environment.
Data output / Output terminals	iExaminer App: Ability to Transfer images via email or print (Performed by the iPhone 4 / 4S operating system)	Image data can be transferred to the PC by using USB connection. USB 1.1 terminal. Compatible with Windows XP/Vista/7.	Image data can be transferred to the PC by using USB connection. USB 1.1 terminal. Compatible with Windows ME/2000/XP.	Image data can be transferred to a PC via a USB memory drive. USB 2.0 terminal	NA
Usage	Prescription Use. Trained personnel within medical or	Prescription Use	Prescription Use	Prescription Use	Prescription Use. Trained personnel within medical or school environment.

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Point of comparison	iExaminer (K121405)	Optomed Smartscope M5 with EY3(K110986)	KOWA Genesis-D (K080681)	EyeQuick EDOC-1000 (HKI, K102412)	Welch Allyn 11800 Ophthalmoscope (K003376)
	school environment.				
Use Conditions	With or without mydriatic	Intended to use without mydriatic but can be used also with mydriatic	With or without mydriatic	With or without mydriatic	With or without mydriatic
Observation light source	As per PanOptic: Halogen lamp, visible light	Visible and infrared LED	Visible LED	Welch Allyn Halogen lamp, visible light	Halogen lamp, visible light. Visible LED
Observation and display system	As per iPhone 4 or 4S: 3.5" widescreen display. 960 x 640 pixel resolution at 326 ppi, 800:1 contract ratio, 500cd/m2 max brightness	2.4" active matrix color TFT LCD	Visual observation	1.75" LCD screen	Visual observation
Photographic light source	As per PanOptic observation light source: Halogen lamp visible light	Visible and infrared LED	Xenon flash lamp	As per observation light source: Welch Allyn Halogen lamp, visible light	NA
Camera spec	5 megapixel / 8 megapixel	5 megapixel	2 megapixel	Less than 1 megapixel	NA
Diopter compensation	As per PanOptic: -20D to +20D	At least -20D to +20D	-15D to +35D	-25D to +40D	-20D to +20D
Apertures	As per Panoptic: Multiple	-	Multiple	Multiple	Multiple
Picture angle	25 degrees	Over 40 degrees	Horizontal 30 degree Vertical 25 degree	8 degrees	25 degrees

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Point of comparison	iExaminer (K121405)	Optomed Smartscope M5 with EY3(K110986)	KOWA Genesis-D (K080681)	EyeQuick EDOC-1000 (HKI, K102412)	Welch Allyn 11800 Ophthalmoscope (K003376)
Storage Media	As per iPhone 4 or 4S: Internal storage capacity.	Flash memory card	Flash memory card	Flash memory	NA
Image data format	As per iPhone 4 /4S: JPEG	JPEG, MPEG-4 (video)	JPEG and uncompressed format	JPEG	NA
Weight	PanOptic: 350g iExaminer adapter: 40g iPhone: 4 ,137g – iPhone 4S 140g	Camera: 400g EY3: 180g	1kg	356g	350g
Power Consumption	As per iPhone 4 / 4S: Built in rechargeable Li-Ion battery As per PanOptic: Re-chargeable battery handle 3.5V	Re-chargeable Ni-MH battery 4.8V	60VAC	Re-chargeable Welch Allyn 711 battery	Re-chargeable battery handle 3.5V
Exposure parameters	As per PanOptic: Compliance with ISO 15004-2	Group 1 instrument according to ISO 15004-2	LED is classified according to IEC 60825-1	Meets ISO 10940	Group 1 ophthalmic instrument compliant with ISO 15004-2

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Clinical:

Clinical data were collected to demonstrate substantial equivalence to establish the image quality as generated by the Welch Allyn iExaminer is accurate enough and carries sufficient imaging details to discern important clinical information.

The clinical trial data established that the images as captured by the Welch Allyn iExaminer are accurate enough and carry sufficient imaging details to discern important clinical information.

Conclusion:

The differences between the iExaminer and Predicate devices as noted above in the summary tables do not impact safety and effectiveness based on the bench tests and clinical trial results. Based on the information presented in this 510(k) premarket notification, Welch Allyn's iExaminer is considered substantially equivalent (as safe, as effective and performs as well as) the currently marketed predicate devices.

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

December 20, 2012

Welch Allyn, Inc.
c/o Mr. Kevin Crossen
Director, Regulatory Affairs
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153

Re: K121405
Trade/Device Name: PanOptic iExaminer
Regulation Number: 21 CFR 882.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: December 13, 2012
Received: December 17, 2012

Dear Mr. Crossen:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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): K121405

Device Name: Welch Allyn PanOptic iExaminer

Indications for Use:

The iExaminer is an attachment and software used only with the iPhone 4 and iPhone 4S in conjunction with the Welch Allyn PanOptic Ophthalmoscope to allow users to capture, send, store and retrieve images of the eye. The device is intended to be used by trained personnel within a medical or school environment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K121405