March 15, 2023

Welch Allyn, Inc.
Jeffrey Thompson
Manager, Regulatory Affairs
(a subsidiary of Baxter Healthcare Corporation)
4341 State Street Road
Skaneateles Falls, New York 13153

Re: K223381
Trade/Device Name: iExaminer System with Panoptic Plus
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: February 17, 2023
Received: February 17, 2023

Dear Jeffrey Thompson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elvin Y. Ng -S

Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223381

Device Name
iExaminer System with PanOptic Plus

Indications for Use *(Describe)*
The iExaminer system with PanOptic Plus, consisting of PanOptic Plus, SmartBracket, SmartClip, iExaminer application, and one of the following: iPhone X, iPhone 11 Pro, iPhone 11 Pro Max, iPhone 12 Pro, is intended to be used to capture images as an aid to clinicians in the evaluation, and documentation of ocular health. The images from the iExaminer System with PanOptic Plus are not intended to be used as a sole means of diagnosis.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

DATE PREPARED: 09 MAR 2023

OWNER:

Welch Allyn Inc. (a subsidiary of Baxter Healthcare Corporation)
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CONTACT PERSON:

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IDENTIFICATION OF THE DEVICE:

Trade/Device Name: iExaminer System with PanOptic Plus
Classification Panel: Ophthalmic
Regulation Number: 21 CFR 886.1120
Regulation Name: Camera, Ophthalmic, Ac-Powered
Regulatory Class: Class II
Product Code: HKI

Table 1. Proposed Model number for iExaminer System with PanOptic Plus

Model Number	Name
901161	iExaminer System with PanOptic Plus

Figure 1. Proposed Product Diagram for iExaminer System with PanOptic Plus

1. PanOptic Plus ophthalmoscope
2. Smart device attachment mechanism (made of SmartBracket and SmartClip)
3. Compatible Smart device
4. iExaminer Pro Software Application

Predicate Device

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
iExaminer with PanOptic	Welch Allyn, Inc.	K121405	December 20, 2012

Description of the Device

The iExaminer System with PanOptic Plus is a medical device that allows the user to capture images through the use of a PanOptic Plus ophthalmoscope and a smart device. The iExaminer System with PanOptic Plus consists of (also see Figure 1):

1. PanOptic Plus Ophthalmoscope:
   a. Ophthalmoscope Head
   b. Compatible energy sources (i.e. battery handles or wall units)
   c. Optional Patient Eyecup
2. Smart device attachment instrument (made of SmartBracket and SmartClip);
3. Compatible smart device (iPhone X, iPhone 11 Pro, iPhone 11 Pro Max, iPhone 12 Pro).

4. iExaminer Pro Software Application.

The iExaminer system with PanOptic Plus is intended to take photographs of the eye and surrounding area.

The device is for prescription use only.

Indications For Use

The iExaminer system with PanOptic Plus, consisting of PanOptic Plus, SmartBracket, SmartClip, iExaminer application, and one of the following: iPhone X, iPhone 11 Pro, iPhone 11 Pro Max, iPhone 12 Pro, is intended to be used to capture images as an aid to clinicians in the evaluation, and documentation of ocular health. The images from the iExaminer System with PanOptic Plus are not intended to be used as a sole means of diagnosis.

Device Comparison and Substantial Equivalence

Table 3. Device Comparison (Proposed vs. Predicate Device)

Characteristic	Predicate – iExaminer with PanOptic (K121405)	Proposed Device – iExaminer System with PanOptic Plus	Discussion of Differences
FDA Product Code	HKI; Camera Ophthalmic, AC-Powered	Same	N/A
FDA Regulation #	21 CFR 886.1120	Same	N/A
Indications for Use/Intended 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.	The iExaminer system with PanOptic Plus, consisting of PanOptic Plus, SmartBracket, SmartClip, iExaminer application, and one of the following: iPhone X, iPhone 11 Pro, iPhone 11 Pro Max, iPhone 12 Pro, is intended to be used to capture images as an aid to clinicians in the evaluation, and documentation of ocular health. The images from the iExaminer System with PanOptic Plus are not intended to be used as a sole means of diagnosis.	The proposed device uses similar hardware components including a different list of smart devices as clearly listed in the Welch Allyn® iExaminer® Pro Ophthalmoscopes Instructions for Use (IFU). The proposed device IFU does not constitute a new Intended Use from the predicate device as both the predicate and the proposed devices are intended to aid the clinician in the evaluation and documentation of ocular health. The use environment and use conditions are the same as the predicate device for which it is intended to be used.
Components	Ophthalmoscope, adapter for aligning smart device optics and ophthalmoscope optics, smart device and the iExaminer software application.	Same	N/A
Compatible Smartphones	iPhone 4, iPhone 4S	iPhone X, iPhone 11 Pro, iPhone 11 Pro Max, and iPhone 12 Pro	The proposed device uses different list of smart devices as clearly listed in the Welch Allyn® iExaminer® Pro

Table 3. Device Comparison (Proposed vs. Predicate Device)

Characteristic	Predicate – iExaminer with PanOptic (K121405)	Proposed Device – iExaminer System with PanOptic Plus	Discussion of Differences
			Ophthalmoscopes Instructions for Use (IFU). The proposed device IFU does not constitute a new Intended Use from the predicate device as both the predicate device and the proposed device are intended to allow users to capture images of the eye. Design control activities have been conducted and confirmed that there is no impact to safety or effectiveness for this application.
Intended Population	Adult, Pediatric	Same	N/A

Table 3. Device Comparison (Proposed vs. Predicate Device)

Characteristic	Predicate – iExaminer with PanOptic (K121405)	Proposed Device – iExaminer System with PanOptic Plus	Discussion of Differences
Prescription Use Only	Yes	Same	N/A
Minimum Pupil Diameter Size	2mm (per PanOptic)	3mm (per PanOptic Plus)	Both ophthalmoscopes provide the ability to function on patients with small pupil sizes.
Working Distance	25.4mm	24.4mm	Both ophthalmoscopes provide a similar working distance.
Pixel Pitch	Measured 5.37 microns for iPhone 4 High Res 4.25 microns for iPhone 4S High Res	Measured Approximately 2 microns for each of the compatible smartphones	Both opthalmascopes provide the appropriate pixel pitch based on the models of iphones used. The proposed device has a lower pixel pitch due to advancements in the resolution of the camera and the telephoto lens.
Optical Magnification	1.183 (per PanOptic)	0.90 (per PanOptic Plus)	Both ophthalmoscopes provide similar magnification (~1x).
Data Output/ Output Terminals	iExaminer App iOS (version 1.0)	iExaminer Pro App iOS (version 4.0.0.13)	Minor differences have been made to the application since the predicate device, but do not impact the safety or effectiveness of the product. Design control activities have been conducted and confirmed that there is no impact to safety or effectiveness for this application.
Use Conditions	With or without mydriatic	Same	N/A

Table 3. Device Comparison (Proposed vs. Predicate Device)

Characteristic	Predicate – iExaminer with PanOptic (K121405)	Proposed Device – iExaminer System with PanOptic Plus	Discussion of Differences
Photographic Light Source	As per PanOptic observation light source: Halogen lamp visible light	As per PanOptic Plus observation light source: LED visible light	See "Observation Light Source" in this table.
Observation Light Source	As per PanOptic observation light source: Halogen lamp visible light	As per PanOptic Plus observation light source: LED visible light	Both provide a light output that allows for the clinician to view anatomy. Also see "Exposure Parameters" in this table below
Observation and display system	As per iPhone 4 or 4S: 3.5" screen size	iPhone X and 11 Pro - 5.8"inch screen size iPhone 11 Pro Max – 6.5" inch screen size iPhone 12 Pro – 6.1" inch screen size	The proposed system includes a larger display, which should permit easier viewing. Other screen parameters of the user's system are verified via the "Test the Resolution" section of the IFU.
Camera Spec	5 megapixel / 8 megapixel	12 megapixels	Both opthalmascopes provide the appropriate camera spec based on the models of iphones used. The proposed device has a higher camera spec due to advancements in the resolution of the camera.
Diopter Compensation	As per PanOptic: -20D to +20D	As per PanOptic Plus: -20D to +25D	PanOptic Plus provides a wider diopter range, which is a benefit to the user.
Apertures	As per PanOptic: Multiple	Same	N/A
Picture Angle	25 degrees	20 degrees	Both provide a relatively large field of view for performing eye exams.

Table 3. Device Comparison (Proposed vs. Predicate Device)

Characteristic	Predicate – iExaminer with PanOptic (K121405)	Proposed Device – iExaminer System with PanOptic Plus	Discussion of Differences
Storage Media	Internal storage capacity	Same	N/A
Exposure Parameters	As per PanOptic: Compliance with ISO 15004-1 as Group 1 (ophthalmic instrument for which no potential light hazard exists)	As per PanOptic Plus: Compliance with ANSI Z80.36 as Group 2 (ophthalmic instrument for which a potential light hazard exists.)	Both devices comply with applicable eye safety standards (e.g. ISO 15004-2 and ANSI Z80.36: 2021) at the time of the respective submission dates.
Image Data Format	JPEG	Same	N/A

DISCUSSION OF NONCLINICAL TESTS:

Non-Clinical testing of the iExaminer System with PanOptic Plus has been performed against requirements for performance, physical attributes, environmental conditions and safety, and to provide objective evidence that the device's intended use is met. A summary of testing performed is identified in the summary below.

- Software: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005.
- Software: Guidance for Off-the-Shelf Software Use in Medical Devices, September 2019.
- Software: General Principles of Software Validation; January 2002.
- FDA Guidance on Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices.
- Biocompatibility: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices--Part 1: Evaluation and testing within a risk management process", Issued June 2016.

The iExaminer System with PanOptic Plus was tested to evaluate its safety and effectiveness based on the standards and associated methods below:

- ISO 10940 (Second edition 2009-08-01) Ophthalmic Instruments—Fundus Cameras
- ANSI Z80.36 (2021) American National Standard for Ophthalmics—Light Hazard Protection for Ophthalmic Instruments
- EN/IEC 62304 (2006/A1:2016) Medical Device Software – Software Life Cycle Processes
- EN/IEC 60601-1-60 (ED 3.1 2013-10) Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard Usability
- IEC 62366-1 (2015+AMD1: 2020) Medical devices – Part 1: Application of usability engineering to medical devices
- EN/ISO 10993-1 (Fifth edition 2018-08) Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process

- EN ISO/ISO 15004-1 (Second edition 2020-5) Ophthalmic Instruments—Fundamental Requirements and Test Methods – Part 1: General Requirements Applicable to all Ophthalmic Instruments
- EN IEC 60601-1-2 (2014) Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility – Requirements and Tests

In addition to the above, and in consideration of IEC 62366-1: 2015+AMD1: 2020, Medical devices – Part 1: Application of usability engineering to medical devices as well as FDA guidance, "Applying Human Factors and Usability Engineering to Medical Devices - Guidance For Industry And Food And Drug Administration Staff (document Issued On: February 3, 2016), results demonstrated that the iExaminer System with PanOptic Plus is suitable for its intended use.

The results of verification and validation demonstrate that the iExaminer System with PanOptic Plus has passed all established acceptance criteria and is as safe and effective as the predicate device for its intended use. Based on the comparison analysis and test results, Welch Allyn has concluded that the iExaminer System with PanOptic Plus to be substantially equivalent to the predicate device.

DISCUSSION OF CLINICAL TESTS:

Image Comparison Study: An image comparison study was performed on the iExaminer System with PanOptic Plus. The primary objective of this study was to demonstrate that the iExaminer System with PanOptic Plus images are substantially equivalent to the predicate device (i.e. PanOptic with iPhone 4/4S and iExaminer (version 1.0) FDA 510(k) K121405) images in their usefulness for documentation and clinical referrals.

The results of the image comparison study demonstrate that the iExaminer System with PanOptic Plus has passed all established acceptance criteria and is as safe and effective as the predicate device for its intended use. Based on the image comparison study results, Welch Allyn has concluded the iExaminer System with PanOptic Plus to be substantially equivalent to the predicate device.

CONCLUSION:

The iExaminer System with PanOptic Plus has been verified and validated against design input requirements, user needs and intended uses. The non-clinical and clinical testing (image comparison study) demonstrate that the subject device raises no new questions

concerning safety and effectiveness, is substantially equivalent, and performs comparably to the predicate device that is currently marketed for the same intended use.