September 26, 2022

PhotoniCare, Inc
Ryan Shelton
CEO
1902 Fox Drive, Suite F
Champaign, Illinois 61820

Re: K222655
Trade/Device Name: OtoSight Middle Ear Scope
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: QJG
Dated: August 31, 2022
Received: September 2, 2022

Dear Ryan Shelton:

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,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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)*
K222655

Device Name
OtoSight Middle Ear Scope

Indications for Use *(Describe)*
The OtoSight Middle Ear Scope is intended for use as an imaging tool for real-time visualization of the human tympanic membrane and fluid or air within the middle ear space. In the presence of middle ear fluid, the OtoSight Middle Ear Scope is used to visualize the fluid density. The OtoSight Middle Ear Scope is also used to provide surface images of the ear canal and tympanic membrane. It is indicated for use in children and adults.

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.

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510k Summary
K222655

1. Information Page

Date Prepared:	August 31, 2022
Submitted by:	PhotoniCare, Inc.
Web:	https://photoni.care/
Address:	PhotoniCare Inc. 1902 Fox Drive, Suite F Champaign, IL 61820
Contact Person:	Ryan Shelton PhD
Phone Number:	(866) 411 3277
Common Name:	Optical Coherence Tomography (OCT) Imaging Otoscope
Proprietary Name:	OtoSight Middle Ear Scope
Classification:	
Regulation Numbers:	21 CFR 892.1560
Name:	Device System, Imaging, Tympanic Membrane and Middle Ear
Code:	QJG
Class:	2
Predicate Device(s):	
Model Name:	TOMiScope (cleared under K191804 as the TOMiScope but commercialized now as OtoSight Middle Ear Scope)
Common Name:	Optical Coherence Tomography Scanner
510(k) #	K191804
Manufacturer:	PhotoniCare, Inc.
Clearance Date:	December 5, 2019
The predicate device has not been subject to a design-related recall.	

2. Device Description

The OtoSight Middle Ear Scope is a multiple use, non-sterile device which provides a surface view of the eardrum, equivalent to the functionality of a video otoscope. Additionally, the OtoSight Middle Ear Scope provides a view through the surface to visualize the contents of the middle ear using Low-Coherence Interferometry (LCI). LCI is an implementation of OCT which, rather than generating 2-D or 3-D images, is limited to the generation of a one-dimensional in-depth density profile displayed over time, which reveals the optical reflective property of the tympanic membrane (TM), as well as the content(s) which are present behind the TM.

The OtoSight Middle Ear Scope has a form factor which allows for ease of imaging the middle ear by the clinician, who will utilize disposable speculum tips and position the OtoSight Middle Ear Scope in the external ear canal in the same way routinely utilized for the current gold standard otoscopy. A push-button on the handheld is used to put the device into active recording mode, capturing both surface and LCI images simultaneously. Scan data is saved on the device with the option to export a summary of the scan over a Wi-Fi network.

The device incorporates a battery that provides 7 hours of use under a typical usage scenario to facilitate convenient use in a practice.

2.1 Intended Use/Indications

The OtoSight Middle Ear Scope is intended for use as an imaging tool for real-time visualization of the human tympanic membrane and fluid or air within the middle ear space. In the presence of middle ear fluid, the OtoSight Middle Ear Scope is used to visualize the fluid density. The OtoSight Middle Ear Scope is also used to provide surface images of the ear canal and tympanic membrane. It is indicated for use in children and adults.

2.2 Technology

Video Otoscopy
To provide a similar viewing experience to the clinician, and to guide LCI signal acquisition, video otoscopy is also integrated. These images are captured by a CCD camera. The otoscopy provides the true color surface image of the ear canal and the TM.

Low-Coherence Interferometry (LCI)
To visualize the in-depth density of human TM, the OtoSight Middle Ear Scope utilizes LCI, a non-invasive, optical imaging technique analogous to ultrasound imaging. Instead of using sound as in ultrasound imaging, LCI uses near infrared light. It is a non-scanning implementation of the more well-known OCT. In academia, LCI specifically refers to OCT technology that doesn't repeatedly steer the imaging optical beam perpendicular to the beam direction.

Where OCT utilizes scanning components to steer the in-depth profiling beam which can generate 2-D or 3-D images, the OtoSight Middle Ear Scope does not use a beam steering component because the in-depth density along the beam direction is sufficient to reveal the middle ear content. LCI, or rather one-dimensional OCT, uses a stationary beam instead to generate a one-dimensional in-depth density profile, over time. LCI reveals the optical reflective property of the TM, as well as the contents present behind.

3. Description of changes

The OtoSight Middle Ear Scope predicate has been available on the US market since October 2020. In that time, it has been used thousands of times. As part of regular interactions with users, feedback has indicated that a more mobile product would benefit use within a typical primary care practice. In particular, it was noted that bringing the product to the exam room and finding a power outlet within reach of the patient was impacting practice workflow. This design change is intended to reduce the impact of the device on the practice workflow by supporting use while on battery power.

Table 1 is a summary of the changes included within the project that is resulting in the application of a Special 510(k) for the modification of the OtoSight Middle Ear Scope. The proposed device was developed according to existing risk management and design and development processes. All new and existing risks have been appropriately mitigated and residual risk is acceptable.

Table 1. List of changes to the device included within this special 510k submission.

Area impacted	Description of changes
Technological Characteristics	Device is operable under battery power for up to 7 hours. Internal battery is a non-user replaceable 74Wh li-ion battery.
Risk Analysis	Risk Management File has been updated to reflect new risks and mitigations introduced into product as part of device changes
Labeling	IFU, Quick Start Guide and device labeling updated to reflect operation under battery power and compliance with additional standards.

4. Non-Clinical Performance Testing

The OtoSight Middle Ear Scope has been tested using appropriate bench testing methods to ensure safety as well as performance aspects. Test results of the subject device have demonstrated that the device performs within its design specifications and equivalently to the predicate device.

Design changes were completed according to the internal PhotoniCare design controls standard operating procedure with appropriate verification and validation completed. For changes that may have impacted conformity to recognized standards, verification was completed to ensure the device remains compliant. Design control procedures provided reasonable assurance of safety and effectiveness and that the modifications did not affect the intended use.

As applicable, the verification and validation testing completed for the design change was equivalent to verification and validation activities completed for the predicate device. Table 2 provide a non-exhaustive summary verification and validation activities completed for the subject device.

Table 2 – Summary of non-clinical performance testing of subject device

Verification/Validation Method	Acceptance Criteria	Summary of results
IEC 60601-1:2005+AMD1:2012 CSV	Compliant with IEC 60601-1 ed3.1	PASS
IEC 62133-2:2017	Compliant with IEC 62133-2:2017	PASS
IEC 60601-1-2 4th edition	Compliant with IEC 60601-1-2 4th edition	PASS
Verification of existing and new design inputs according to existing protocols equivalent to used in K191804.	Equivalent to acceptance criteria used in K191804, as applicable.	PASS
Validation of existing and new user needs according to equivalent protocol used in K191804.	Equivalent to acceptance criteria used in K191804, as applicable.	PASS

5. Substantial Equivalence

The OtoSight Middle Ear Scope has the same intended use, indications for use and fundamental technology as the predicate. The design change included in the submission impacts only the use of the device on battery, and associated design and labeling changes to facilitate the change in operation.

Verification and validation activities have shown adherence to the original design inputs and user needs using the same methods and acceptance criteria, as applicable, with substantially equivalent performance to the predicate.

6. Conclusion

The OtoSight Middle Ear Scope is substantially equivalent in intended use and fundamental scientific technology to its predicate. The OtoSight Middle Ear Scope is considered as safe and effective as the predicate device for its intended use when used in accordance with its Instructions

for Use.

The rechargeable battery does not introduce different issues of safety and effectiveness of the device. Non-clinical performance data, conformity to standards, and risk analysis provides evidence to support reasonable assurance of safety and effectiveness per its intended use and is substantially equivalent to the predicate.