December 5, 2019

PhotoniCare, Inc.
Ryan Shelton, Ph.D.
CEO
60 Hazelwood Dr.
Champaign, Illinois 61820

Re: K191804
Trade/Device Name: TOMi Scope
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: QJG
Dated: October 25, 2019
Received: November 5, 2019

Dear Dr. 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,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191804

Device Name
TOMi Scope

Indications for Use *(Describe)*
The TOMi 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 TOMi Scope is used to visualize the fluid density. The TOMi 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5—510(k) Summary

Provided in accordance with 21 CFR 807.92

1. General Provisions

Date Prepared:

December 5, 2019

Submitted by:

PhotoniCare, Inc.

Web: https://photoni.care/

Contact Person:

Ryan Shelton PhD, CEO and Co-founder PhotoniCare, Inc.

Common Name:

Optical Coherence Tomography (OCT) Imaging otoscope

Trade/Proprietary Name:

Model 34R TOMi Scope

Establishment Registration Number:

N/A

Classification:

Regulation Numbers: 21 CFR 892.1560
Name: Ultrasonic pulsed echo imaging system
Product code: QJG

Class II

Predicate Device:

(Primary)

Model Name:	Foresee (4C) Imaging System
Common Name:	Optical Coherence Tomography Scanner
510(k) #	K133209
Manufacturer:	Diagnostic Photonics, Inc.
Submitted:	October 17, 2013

Reference Device:

Model Name: AIO HD Otoscope

Common Name: Otoscope

510(k) #K123821

Manufacturer: Blue Focus

Submitted: December 12, 2012

To our knowledge, the predicate and reference devices have not been subject to a design-related recall.

2. Description and Use

Model 34R TOMi 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 TOMi 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 TOMi Scope has a form factor which allows for ease of imaging the middle ear by the clinician, who will utilize disposable specula tips and position the TOMi 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.

Device Components/Accessories

The TOMi Scope System includes the following components:

- Base unit with touch screen
- Handheld piece with visual display
- Opto-electrical connection cable
- Stand
- Power cord

The TOMi Scope utilizes software which is responsible for the user interface. The user interface consists of both user inputs and displayed information.

The following accessories are available for the TOMi Scope:

- TOMi Adult Speculum Tip
- TOMi Pediatric Speculum Tip

Environment of Use

The TOMi Scope is intended to be used in a healthcare facility by qualified users.

3. Intended Use / Indications Statement:

The Tomi 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 TOMi Scope is used to visualize the fluid density. The TOMi Scope is also used to provide surface images of the ear canal and tympanic membrane. It is indicated for use in children and adults.

While the Indications for Use Statement for the TOMi Scope is not identical to the predicate device, the differences do not alter the intended use of the device nor do they affect the safety and/or effectiveness of the device relative to the predicate. Both the subject device and the primary predicate device utilize equivalent technology to produce images which are intended to be evaluated by the clinician. (Note: The video otoscopy functionality of the TOMi Scope is currently considered to be Class 1, 510(k) exempt.)

4. Technological Characteristics

The TOMi Scope includes two fundamental modes of operation; video otoscopy and LCI. These technologies are described below.

Video Otoscopy

In order 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.

(Note: The video otoscopy functionality of the TOMi Scope is currently considered to be Class 1, 510(k) exempt. The AIO HD Otoscope which was cleared under K123821 is included in this submission as a Reference Device.)

Low-Coherence Interferometry (LCI)

To visualize the density profile of the TM and middle ear contents, the TOMi 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 technology.

Technological Characteristic Comparison with Predicate Device

Areas of Comparison	**Subject Device: TOMi Scope**	**Primary Predicate Device: Foresee (4C) Imaging System (K133209)**	**Similarities and Differences**
Measurement Technology	Low-Coherence Interferometry (LCI, one-dimensional Optical Coherence Tomography, 1D-OCT)	Optical Coherence Tomography (OCT)	**Equivalent** LCI is a non-scanning implementation of the more well-known OCT. OCT utilizes scanning components to steer the in-depth profiling beam which can generate 2-D or 3-D images. LCI, or rather one-dimensional OCT, uses a stationary beam instead to generate a one-dimensional, in-depth density profile, displayed over time. LCI reveals optical reflective property of

Areas of Comparison	Subject Device: TOMi Scope	Primary Predicate Device: Foresee (4C) Imaging System (K133209)	Similarities and Differences
			the tympanic membrane, as well as contents present behind.
Light Source	Superluminescent Light Emitting Diode (SLED)	Swept Laser Source	**Equivalent** Both light sources are suitable for OCT
Radiation Type	Near-Infrared Low-Coherence Beam (700 nm - 1400 nm)	Near-Infrared Low-Coherence Beam (700 nm - 1400 nm)	**Same** Same optical radiation band
Optical Radiation Safety Cont. from above.	Class 3R	Class 1	**Different** While the subject device has a higher laser classification than the primary predicate device, the subject TOMi Scope also follows IEC 60825-1 Laser safety standards and employs the following controls: ● unintentional exposures would rarely reflect worst-case conditions of (e.g.) beam alignment with a large pupil and worst-case accommodation with the entire beam energy entering the eye, ● inherent reduction factor (safety margin) in the Maximal Permissible Exposure,

Areas of Comparison	Subject Device: TOMi Scope	Primary Predicate Device: Foresee (4C) Imaging System (K133209)	Similarities and Differences
			● There is a radiation label near the Laser aperture with the warning phrase to avoid eye exposure. The label is readily visible when operating the handheld probe, where the Laser beam is emitting; ● There is a Laser-ON indicator to warn the operator when the Laser is turned on; ● There are instructions in the Instruction for Use (IFU), which asks the operator to avoid pointing the handheld probe towards the eye; ● While the TOMi Scope uses a laser in the near infrared wavelength range, there are LEDs in the visible wavelengths for illumination of the tympanic membrane. The illumination is ON when the Laser is turned on. Such illumination causes natural aversion behavior of human eye to avoid bright light exposure.

Areas of Comparison	Subject Device: TOMi Scope	Primary Predicate Device: Foresee (4C) Imaging System (K133209)	Similarities and Differences
Reference Arm	Fixed reference arm	Fixed reference arm	**Same**
Optical Signal Detection	Frequency-domain signal acquisition	Frequency-domain signal acquisition	**Same**
Axial Resolution	≤ 47µm (in air)	< 20 µm (in air)	**Equivalent** OCT devices have a trade-off between the axial resolution and the axial imaging range. For TOMi Scope we accept a lower axial resolution, which is still sufficient to represent the eardrum thickness on the order of one hundred microns. We designed a longer axial imaging range which makes the device more user friendly in the tortuous ear canal. Nevertheless, the two parameters are on the same order of magnitude.
Axial Imaging Range	≥ 3mm (in air)	≥ 2.1mm (in air)	**Equivalent** OCT devices have a trade-off between the axial resolution and the axial imaging range. For the TOMi Scope we accept a lower axial resolution, which is still sufficient to represent the eardrum thickness on the order of one hundred microns.

Areas of Comparison	Subject Device: TOMi Scope	Primary Predicate Device: Foresee (4C) Imaging System (K133209)	Similarities and Differences
			We design a longer axial imaging range which makes the device more user friendly in the tortuous ear canal. Nevertheless, the two parameters are on the same order of magnitude as the predicate device.
Lateral Resolution	≤ 50μm	< 20μm	**Equivalent** The comparison of the lateral resolution and lateral scanning range is a comparison between general OCT versus LCI. Lateral direction is perpendicular to the beam direction. Because LCI does not scan laterally or identify lateral features, the lateral resolution is less critical for the TOMi Scope. Nevertheless, the two lateral resolutions are on the same order of magnitude.
Lateral Scanning Range	None (1D-OCT)	9.6mm	**Different** The comparison of the lateral resolution and lateral scanning range is a comparison between general OCT versus LCI. Lateral direction is perpendicular to the beam direction.

Areas of Comparison	Subject Device: TOMi Scope	Primary Predicate Device: Foresee (4C) Imaging System (K133209)	Similarities and Differences
			LCI does not scan laterally, because the features of interest in the ear application are in the axial dimension, rather than the lateral dimension, so the TOMi Scope was designed without lateral scanning to simplify the usability and design complexity. Despite this technological difference from the predicate device, bench and clinical testing demonstrated the PhotoniCare TOMi Scope performs as intended.
Power Supply	120/240V, 50/60Hz	120/240V, 50/60Hz	**Same**
Luminance Measurement and Light Intensity	10 cm: 125 lux 15 cm: 84 lux 20 cm: 49 lux	N/A	**Equivalent** TOMi Scope uses lower luminance than the AIO HD otoscope. Nevertheless, the luminance is on the same order of magnitude.
LED Operating Voltage	4V	N/A	**Equivalent** TOMi Scope uses a lower voltage for electronic parts inside the hand-held unit which includes the APPLIED PART (speculum tip)

Areas of Comparison	Subject Device: TOMi Scope	Primary Predicate Device: Foresee (4C) Imaging System (K133209)	Similarities and Differences
Contact Temperature	34.4 ℃ (93.92 F)	N/A	**Equivalent** The TOMi Scope contact temperature is slightly higher than the AIO HD otoscope but is within a comfortable range which does not pose additional risks.

5. Performance Data

The TOMi Scope has been designed and tested to comply with all applicable FDA Recognized Standards. The following table provides a listing of the recognized standards to which TOMi Scope conforms.

Standard ID #	Title	FDA Recognition #
IEC 60601-1:2005+AMD1:2012 CSV	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	19-4
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-8
IEC 60601-1-6:2010+AMD1:2013 CSV	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89
IEC 60825-1:2007	Safety of laser products - Part 1: Equipment classification and requirements	12-273
IEC 62471:2006	Photobiological safety of lamps and lamp systems	12-249
IEC 62304:2006+AMD1:2015 CSV	Medical device software - Software life cycle processes	13-79
ISO 10993-1:2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2-220

6. Non-Clinical Testing

A non-clinical bench study using a phantom ear comprised of a model tympanic membrane and middle ear fluid of varying densities demonstrated that the TOMi Scope visualizes the phantom tympanic membrane and fluid as intended. Comprehensive verification and validation testing was also performed on the device in accordance with the requirements of regulation Part 21 CFR 820.30, in order to confirm that it is safe and functions as intended.

7. Clinical Testing

The following non-clinical performance testing was submitted in support of the substantial equivalence determination.

PhotoniCare conducted a 26 subject, single site clinical study involving both Pediatric and Otolaryngology clinics to illustrate the ability of the TOMi Scope to collect images of human

tympanic membrane (TM; eardrum) and underlying middle ear space, from adult and child subjects in a clinical setting.

The intent of this observational study was to illustrate the ability of the TOMi Scope to collect images of human TM and underlying middle ear space in the proposed adult and child patient population.

The two endpoints for the study were:

- Endpoint 1: Obtain data illustrating the clinical use of the PhotoniCare TOMi Scope to collect bilateral images of human TM and underlying middle ear space from at least 25 combined adult and child subjects.
- Endpoint 2: Obtain data illustrating TOMi Scope imageability of human middle ears, wherein at least 80% of TOMi Scope images collected are considered readable by a trained reader.

Both endpoints were successfully achieved.

8. Summary/Conclusion

Based upon conformity to applicable FDA recognized standards, non-clinical and clinical performance testing as well as the result of the risk assessment, the TOMi Scope was found to have a safety and effectiveness profile that is equivalent to the predicate device. Therefore, PhotoniCare, Inc. has demonstrated that the TOMi Scope is substantially equivalent to the stated predicate device and that the TOMi Scope is as safe and performs in an equivalent manner to the stated predicate device.