September 2, 2020

OptoMedical Technologies GmbH
% Oliver Eikenberg
Senior Consultant QA/RA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K200516
Trade/Device Name: OCT-Camera ID 21101A3
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO
Dated: July 27, 2020
Received: July 28, 2020

Dear Oliver Eikenberg:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200516

Device Name
OCT-Camera ID 21101A3

Indications for Use *(Describe)*

OptoMedical Technologies OCT-Camera ID 21101A3 is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT). The OCT-Camera ID 21101A3 is indicated for the use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on all patient populations except premature and neonatal infants, and is suitable for patients ambulatory or confined. The system is indicated for use in supine imaging, mounted to the surgical microscope HS Hi-R NEO 900A NIR (Haag-Streit), and is suited for imaging patients under anesthesia.

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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510(k) Summary

OCT-Camera ID 21101A3

K200516

1. Submission Sponsor

OptoMedical Technologies GmbH

Maria-Goeppert-Strasse 9

23562 Luebeck, Germany

Phone: +49 451 160865 00

Contact: Julia Behrens, Quality and Regulatory Affairs Manager

E-mail: behrens@opmedt.com

2. Submission Correspondent

Emergo Global Consulting, LLC

2500 Bee Cave Road

Building 1, Suite 300

Austin, TX 78746

Office Phone: (512) 327.9997

Email: LST.AUS.ProjectManagement@ul.com

Contact: Oliver Eikenberg, PhD

Title: Senior Consultant, Quality & Regulatory Affairs

3. Date Prepared

09/02/2020

4. Device Identification

Trade/Proprietary Name(s): OCT-Camera ID 21101A3

Common/Usual Name: intraoperative Optical Coherence Tomography (iOCT)

Classification Name: Ophthalmoscope, AC-powered; Tomography, Optical Coherence

Regulation number: 21 CFR 886.1570

Product Code: OBO

Device Class: Class II

Classification Panel: Ophthalmic

5. Legally Marketed Predicate Device

K142953, OCT-Camera (ID21101A1), OptoMedical Technologies GmbH, GERMANY

6. Indication for Use Statement

OptoMedical Technologies OCT-Camera ID 21101A3 is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT).

The OCT-Camera ID 21101A3 is indicated for the use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on all patient populations except premature and neonatal infants, and is suitable for patients ambulatory or confined.

The system is indicated for use in supine imaging, mounted to the surgical microscope HS Hi‑R NEO 900A NIR (Haag-Streit), and is suited for imaging patients under anesthesia.

7. Device Description

The **OCT-Camera ID 21101A3** can connected via the camera port of surgical microscopes. The **OCT-Camera ID 21101A3** is completely integrated into the surgical procedure by enabling the OCT imaging before, during, and after microsurgery without disrupting the microscopic view. Individual steps of surgical procedures can be visualized in real time.

The **OCT-Camera ID 21101A3** by OptoMedical Technologies GmbH facilitates the intraoperative use of OCT (iOCT). It is called **OCT-Camera ID 21101A3,** because it can be attached to the camera port of an operating microscope like any common camera that are used for the purpose of providing live view images of the surgical field.

8. Substantial Equivalence Discussion

The following table compares the **OCT-Camera ID 21101A3** to the predicate device **OCT-Camera (ID 21101A1)** with respect to indications for use, principles of operation, technological characteristics and performance specifications.

The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics between Subject Device and Predicate Device

	Subject Device	Predicate Device (K142953)	Device Comparison
Manufacturer	**OptoMedical Technologies GmbH (GERMANY)**		
Trade Name	**OCT-Camera ID 21101A3**	**OCT-Camera (ID 21101A1)**	
Product Code	OBO		***Same***
Regulation Number	886.1570		**Same**
Regulation Name	Ophthalmoscope		***Same***
Professional Use	Yes		***Same***
Indications for Use	OptoMedical Technologies OCT-Camera ID 21101A3 is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT). The OCT-Camera ID 21101A3 is indicated for the use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on all patient populations except premature and neonatal infants, and is suitable for patients ambulatory or confined. The system is indicated for use in supine imaging, mounted to the surgical microscope HS Hi-R NEO 900A NIR (Haag-Streit), and is suited for imaging patients under anesthesia.	OptoMedical Technologies OCT-Camera is intended to acquire, process, display and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography (SD-OCT). The OCT-Camera is indicated for the use as an aid in the diagnosis of physiologic and pathologic conditions of the eye through non-contact optical imaging. Imaging of the various tissues of the eye is supported through the use of interchangeable lenses. It is indicated for use on patient populations from premature and neonatal infants to adult, and is suitable for patients ambulatory or confined. The system is indicated for use in supine imaging, mounted to the surgical microscope HS Hi-R NEO 900A NIR (Haag-Streit), and is suited for imaging patients under anesthesia.	***Similar*** *Excluded target population of premature/ neonatal infants as risks for those patient groups were not further evaluated for this target group.*
Method of Operation	Spectral domain optical coherence tomography (SD-OCT)		***Same***
Sterile	no		***Same***
Scanner Ergonomics	Mounted to camera port of the surgical microscope HS Hi-R NEO 900A NIR		***Same***
Patient Interface	none		***Same***
Single-Use	no		***Same***
Shelf Life	10 years		***Same***
Battery Operated	no		***Same***
AC Powered	yes		***Same***
Light Hazard Protection	ANSI Z80.36-2016	ANSI Z80.36-2016	***Same***
Electrical Safety Testing	IEC 60601-1, IEC 60601-1-2		***Same***
Laser Product Equipment Classification	OCT-Scanner and OCT-Camera equates to Laser Class 1		***Same***

Table 5A – Comparison of Technological Characteristics between Subject Device and Predicate Device

	Subject Device	Predicate Device	Device Comparison
Manufacturer	**OptoMedical Technologies GmbH (GERMANY)**		
Trade Name	**OCT-Camera ID 21101A3**	**OCT-Camera (ID 21101A1)**	
Technological characteristics			
Light Source	SLED	SLED	***Same***
Light Source Classification	Class 1 LED	Class 1 LED	***Same***
Laser	830 nm	840 nm	***Similar***
Optical Power (OCT Light)	≤1500 µW at cornea during OCT scan	≤2350 µW at cornea during OCT scan ≤47 µW at cornea without scanning	***Similar*** *complies with US-recognized standards IEC 60825-1 and ANSI Z80.36-2016.*
Optical Power (Pilot Light)	N/A	<50 µW at cornea	***Similar***
Resolution, Lateral	Retina: 10.6 to 74 µm in tissue, dependent on magnification of microscope and its retina lens Anterior Segment: 10.6 to 37 µm, dependent on magnification of microscope	Retina: 10.6 to 74 µm in tissue, dependent on magnification of microscope and its retina lens Anterior Segment: 10.6 to 37 µm, dependent on magnification of microscope	***Same***
Resolution, Axial	≤ 7.5 µm in tissue	≤ 10 µm in tissue	***Similar***
Depth Range (in tissue/in air)	2.8 / 3.8 mm	3.1 / 4.2 mm	***Similar***
Scanner Type	Galvanometric Mirror Pair	Galvanometric Mirror Pair	***Same***
Scan Patterns	Line, rectangular volume, cross scan	Line, rectangular volume	***Similar***
Scan Pixels	Axial (depth): 1024 Lateral: fixed to 1000 A-Scans/B-Scan Max. 100000 total A-Scans/Volume-Scan	Axial (depth): 1024 Lateral: fixed to 1000 A-Scans/B-Scan Max. 30000 total A-Scans/Volume-Scan	***Similar***
Scan Rate	35000 A-Scans/s	15000 A-Scans/s	
Detection	Transmission Grating, Spectrometer / Line Scan Camera	Transmission Grating, Spectrometer / Line Scan Camera	***Same***
Footprint	(H x W x D) 6.5” x 15.8” x 13.4”	(H x W x D) 6.5” x 15.8” x 13.4”	***Same***
Scanner Dimensions	(H x W x D) 3.5” x 2.4” x 6.7”	(H x W x D) 3.5” x 2.4” x 6.7”	***Same***
Software	iOCT-Control3	iOCT-Control3	***Same***
Operating System	Win7	Win XP	***Similar*** .
Processor (frequency) / Memory (RAM)	3.1 GHz Core i7 Quad Core 16 GB	2.66 GHz Dual Core 4 GB	***Similar***

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of **OCT-Camera ID 21101A3** and in showing substantial equivalence to the predicate device that are subject to this 510(k) submission, Optomedical Technologies GmbH completed a number of non-clinical performance tests. The **OCT-Camera ID 21101A3** meets all the requirements for overall design, function, performance and electrical safety as well as biocompatibility and internal requirements (incoming control, final release testing) confirming that the design output meets the design inputs and specifications for the device and to support substantial equivalence of the subject device.

OptoMedical Technologies GmbH passed all the following testing for **OCT-Camera ID 21101A3** in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility evaluation per ISO 10993-1demonstrate that there is no direct patient-contacting materials
- Electrical safety testing per ANSI/AAMI ES 60601-1, PASSED required testing
- Electromagnetic Compatibility testing per IEC 60601-1-2, PASSED required testing
- Laser Safety testing per IEC 60825-1, PASSED required testing
- Light Hazard Protection Testing for Ophthalmic Instrument per ANSI Z80.36-2016, PASSED required testing
- Software verification and validation testing has been completed on a functional level for a Moderate Level of Concern software including system compatibility testing, risk analysis per IEC 62304/FDA Guidance, PASSED required testing
- Usability engineering testing per IEC 62366-1, PASSED required testing
- Risk Management per EN ISO 14971; all requirements were met and risks reduced as far as possible.

10. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the minor differences between the subject device **OCT-Camera ID 21101A3** and the predicate device **OCT-Camera (ID 21101A1)** do not raise new or different questions of safety and effectiveness. Technical product characteristics, performance testing and compliance with voluntary standards demonstrate that the **OCT-Camera ID 21101A3** device is substantially equivalent to the predicate device in terms of design, function, components, materials, principals of operation, performance characteristics, and intended use/indication.