

APR 11 2014

K134039

### 510(k) SUMMARY

**Traditional 510k Summary** Optos Daytona ICG (P200TICG) Device

**Name of Device:** Daytona ICG Ophthalmoscope (P200TICG)

**Common or Usual Name:** Scanning laser ophthalmoscope

**Classification Name:** Scanning laser ophthalmoscope (per 21 C.F.R. § 866.1570)

**Product Code:** MYC

**Submitter:** Optos plc,  
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**Date Prepared:** April 10, 2014

**Predicate Device:** Heidelberg Retina Angiography 2 (K971671)

#### Indications for Use

The Daytona ICG scanning laser ophthalmoscope is indicated for use as a wide field scanning laser ophthalmoscope for viewing choroidal circulation patterns that are illuminated using indocyanine green dye and for aiding both in the assessment of choroidal circulation and in the diagnosis of choroiditis or choroidal diseases.

#### Device Description

The Optos P200TICG is a scanning laser ophthalmoscope that uses a laser as a light source to illuminate the eye. The device consists of the following components and accessories:

- A scanhead which houses the lasers, the scanning elements of the light input path and the light return path including the detectors which convert light into electronic signal. With the exception of the chin support, the scanhead forms the key patient interface with a facepad and associated aperture where the eye is placed and a griphandle at each side of the scanhead. The image capture is controlled by a computer and associated embedded software including a safety module within the scanhead. This software runs on a Linux operating system.
- A chin support is juxta-positioned to the scanhead to support the patient head and reduce patient movement when the eye is placed at the aperture of the scanhead.

- A touchscreen is attached by a cable to the scanhead to assist the operator in optimal patient positioning and to initiate an image capture. An image is displayed on the screen to allow the operator to confirm a suitable image has been taken.
- A personal computer with a monitor to allow image review and storage in a Windows environment.

### **Principles of Operation and Technological Characteristics**

The Optos P200TICG uses light that is scanned by a deflection system in two axes across the layers of the eye to generate an image. The returned light then travels back along the same path to a light detector that converts the light to an electrical signal. This electrical signal is digitized and used to build up an electronic picture in a computer and output on a display screen.

A summary of the safety system is as follows:

- Fast scan idle speed monitored. Power only supplied to beam delivery module if idle speed >7000rpm.
- Fast scan operating speed monitored. Laser enable only permitted if fast scan speed >30,000rpm
- Laser status monitored. Any conflict in laser status results in a system trip.
- Laser powers monitored. If laser power is outside 25% of the nominal power, the system will trip.
- Shutter status monitored. If conflict detected, system will trip.
- Line start rate monitored as back up to fast scan speed monitor (this detects that the light pulse is not static).

The fast scan and line start signals are implemented as low-voltage differential signalling (LVDS signals) to prevent failure occurring and all functionality is monitored on dual channels. All monitoring and decision making is implemented in discrete logic.

The layer of the eye viewed is determined by the wavelength of the laser utilized to illuminate the eye and the return path configured for the light either reflected and/or emitted by fluorescence. For the P200TICG, the laser illuminating the eye is infrared and the returned light is the fluorescence signal induced by the injection of indo cyanine green (ICG) dye. The detector used to capture this signal is optimized to detect infrared light and a filter is used to transmit only the fluoresced infra-red light which is at a slightly longer wavelength than the incident infra-red light entering the eye. This change in wavelength is a fundamental property of fluorescence.

### **Performance Data**

In all instances, the Optos Daytona ICG device functioned as intended and compliance to electrical safety, light safety and biocompatibility has been established. The software development lifecycle and the associated verification & validation activities have no unresolved major or critical bugs and complied with IEC 60601-1-4. The light captured from the return path and translation to an electrical signal was as expected. Additionally this signal has the grey scale/ pixel characteristics to generate a satisfactory image over the indocyanine green (ICG) concentrations found in blood during an ICG angiography exam.

A summary of the testing supporting this conclusion follows:

### *Ex Vivo testing*

The use of equine blood with various concentrations of ICG pervading through a phantom eye was used to determine than an adequate pixel/grey scale range can be achieved to generate an image. This is for indocyanine green blood concentrations ranging from 0.05 mg/L to 50 mg/L. In vivo concentrations during an indocyanine procedure peak at approximately 25-30 mg per liter of blood.

### *Electrical Safety testing (general and electromagnetic compatibility)*

The Daytona ICG device meets the requirements of IEC 60601-1. There were no procedure deviations, no non-standard test methods were used and no additional testing deemed necessary.

The Daytona is compliant to the specification IEC 60601-1-2 and 47 CFR Part 15 subpart B with no abnormalities or departures from the standard conditions.

### *IEC 60825 (Light Hazard standard)*

The Optos device is class I to standard IEC 60825. Class I is the lowest, safest classification.

### *ISO 10993 (Biocompatibility)*

As per ISO 10993-1 the contact is surface, intact skin for a limited duration ( $\leq 24$  hours), requiring cytotoxicity, sensitization and irritation or intracutaneous reactivity. The patient contact points are the face pad and the chin cup and handgrips. The results are tabulated as follows:-

<b>Material</b>	<b>Test</b>	<b>Result</b>
Face pad	Cytotoxicity test ISO 10993-5	Test article not considered to have cytotoxic potential
Face pad	Tests for irritation and skin sensitization ISO 10993-10, intracutaneous injection	Test article sites did not show a significantly greater biological rate than control
Face pad	Tests for irritation and skin sensitization ISO 10993-10, Kligman sensitization	A grade 1 sensitization rate is not considered significant and the test article meets the requirement
Chin cup and handgrips	Cytotoxicity test ISO 10993-5	Test article not considered to have cytotoxic potential
Chin cup and handgrips	Tests for irritation and skin sensitization ISO 10993-10, intracutaneous injection	Test article sites did not show a significantly greater biological rate than control
Chin cup and handgrips	Tests for irritation and skin sensitization ISO 10993-10, Kligman sensitization	A grade 1 sensitization rate is not considered significant and the test article meets the requirement

### *ISO 15004-2: Ophthalmic Instruments, light hazard protection*

The device is a group 1 ophthalmic instrument.

*IEC 60601-1-4 Medical electrical equipment. General requirements for safety. Collateral standard. General Requirements for programmable electrical medical systems.*

*The product has been found to comply with the requirements of this specification.*

### **Substantial Equivalence**

The Daytona ICG (P200TICG) device is as safe and effective as the predicate device, the Heidelberg Retina Angiography 2 (K971671).

The Panoramic Daytona ICG (P200TICG) has the same intended use and indications for use and similar principles of operation and technological characteristics as the predicate device for choroidal angiography. The predicate device also uses an infra-red light source of similar wavelength, requires an injection of indocyanine green dye, and is dependent on the fluorescent properties of this dye in the generation of images appropriate for aiding in the assessment of choroidal circulation and diagnosis of choroiditis or choroidal diseases. Similar to the Optos P200TICG, the predicate device requires the laser to be scanned horizontally and vertically and requires a filter in front of a detector to select only the fluorescent signal for detection. The detection converts the light to an electronic signal for subsequent display on a screen.

The predicate device is of similar construction and being an optomechanical electronic device utilizing a laser(s) is subject to the same general electrical, light hazard and software standards for such medical electrical equipment. Additionally, both the Optos and predicate device are class I in terms of laser power at the eye as defined by IEC 60825 so both devices are dependent on comparable incident light levels to possess this functionality.

The table below provides a side-by-side comparison of the Optos and predicate device:

**OPTOS PLC  
DAYTONA ICG (P200TICG)  
SUBSTANTIAL EQUIVALENCE CHART**

<b>Device</b>	<b>Daytona ICG (P200TICG)</b>	<b>Heidelberg Retina Angiograph 2</b>
Device	Daytona ICG (P200TICG)	Heidelberg Retina Angiography 2
Common Name	Scanning Laser Ophthalmoscope	Scanning Laser Ophthalmoscope
510(k) number	Pending	K971671
Materials	No flammable materials are used near the light source.	No flammable materials are used near the light source.
Max. Temperature of accessible	Does not exceed ambient by more than 10°C.	
Intended Use	To provide images that aid in examining the eye	To provide images that aid in examining the eye
Indications for Use	A wide field scanning laser ophthalmoscope for viewing choroidal circulation patterns that are illuminated using indocyanine green dye and for aiding both in the assessment of choroidal circulation and in the diagnosis of choroiditis or choroidal diseases	Device is intended for viewing the retinal and/or choroidal circulation patterns that are illuminated using fluorescein or indocyanine green dye, and for aiding in the: <ul style="list-style-type: none"> <li>• Management of age-related macular degeneration (AMD)</li> <li>• Detection of choroidal neovascularization (CNV)</li> <li>• Assessment of diabetic retinopathy</li> <li>• Assessment of diabetic maculopathy</li> <li>• Treatment control of diabetic maculopathy, AMD, CNV</li> <li>• Detection of retinal vascular diseases</li> <li>• Assessment of choroidal circulation</li> <li>• Diagnosis of choroiditis or choroidal diseases</li> <li>•</li> </ul>
Method of Operation	Confocal laser scanning system; laser light source; deflection system; scans in two orthogonal axes of the retina; photosensitive device that converts light into image of retina; display system	Confocal laser scanning system; laser light source; deflection system; scans in two orthogonal axes of the retina; photosensitive device that converts light into image of retina; display system

<b>Device</b>	<b>Daytona ICG (P200TICG)</b>	<b>Heidelberg Retina Angiograph 2</b>
Technological Characteristics	Scanning laser ophthalmoscope	Scanning laser Ophthalmoscope
Light Source	Laser	Laser
Wavelength and Color of Light	802 nm infra-red	488nm; blue 790nm; infrared
Exposure Parameters/laser class	Class 1 to IEC 60825	Class 1 to IEC 60825
Number of lasers Used per scan	1	1 or 2
Fixation Pattern	Array of LED's Group 1 to ISO15004-2	Array of LED's
Brightness Controls	Exempt from requirements as a Class 1 laser	Exempt from requirements as a Class 1 laser
Cleaning and disinfection/sterilization	Sterilization not required. Clean/disinfect contact points	Non optical surfaces can be disinfected
Point of contact	Chin rest, face pad and grip handles	Chin & head rest
Data collection and/or display system	Light sensitive detector that converts light into electrical signal. Signal digitised and computer or electronic imaging device to convert digital image for display	Light sensitive detector that converts light into electrical signal. Signal digitised and computer or electronic imaging device to convert digital image for display
External field of view	120°	15°, 20°, 30°
Internal field of view	200°	N/A
Wide Angle Digitised Image Size	3900x3072 pixels	High speed:768x768 pixels at 30° ; High Resolution: 1536x1536 pixels at 30°
Pupil Dilation	Normally advised for ICG but determined by practitioner	Normally advised for ICG but determined by practitioner
Mains current AC 115/240V	6.3A	230V 1.25AT 110V 2.5AT
Approx. weight	Scanhead 27 kg	
Dimensions (l x w x h)	500mm x 440mm x x795mm	N/A
Power Source	Mains powered	Mains powered
Safety Features	Laser overpower and correct functioning of scanning elements	Laser overpower and correct functioning of scanning elements
Biocompatibility	Contact points meet short duration intact skin ISO 10993-1 criteria	Not known, but similar contact points
Software	Embedded and application	Embedded and application
Standards with which the Device Complies	IEC 60601-1, -1-2,-1-4, ISO 10993, ISO 15004-2, IEC 60824	IEC 60601-1, IEC 60601-1-2, IEC 60825

The minor technological differences between the P200TICG and the predicate device do not raise any new questions of safety and effectiveness. Performance data demonstrate that the Optos P200TICG is as safe and effective as the Heidelberg Retina Angiography 2 (K971671) Scanning Laser Ophthalmoscope (SLO).

Thus, the Optos Daytona ICG (P200TICG) Ophthalmoscope is substantially equivalent to legally marketed Heidelberg Retina Angiography 2 (K971671) Scanning Laser Ophthalmoscope (SLO).

### **Conclusions**

The Optos Daytona ICG (P200TICG) has similar characteristics as determined by electrical, light hazard and biocompatibility type testing. Additionally the laser light wavelength, fluorescence barrier filter and non-clinical signal profiling demonstrate that the device is substantially equivalent to the predicate device.



April 11, 2014

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Optos plc  
% Mr. Randy J. Prebula, JD  
Partner  
Hogan Lovells, US LLP  
Columbia Square  
555 Thirteenth Street, NW  
Washington, DC 20004

Re: K134039

Trade/Device Name: Daytona ICG (P200TICG) Ophthalmoscope (Model A10642)  
Regulation Number: 21 CFR 886.1570  
Regulation Name: Ophthalmoscope  
Regulatory Class: Class II  
Product Code: MYC  
Dated: March 6, 2014  
Received: March 6, 2014

Dear Mr. Prebula:

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 contact 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>. 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 <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,

Kesia Y  Alexander -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
**Indications for Use**

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement on last page

510(k) Number (if known)

**K134039**

Device Name

**Daytona ICG (P200TICG)**

Indications for Use (Describe)

The Daytona ICG scanning laser ophthalmoscope is indicated for use as a wide field scanning laser ophthalmoscope for viewing choroidal circulation patterns that are illuminated using indocyanine green dye and for aiding in both the assessment of choroidal circulation and in the diagnosis of choroiditis or choroidal diseases.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**Marsha L. Burke Nicholas -S**

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