SECTION 6
510(k) SUMMARY

510(k) Notification K100019

GENERAL INFORMATION

Applicant:
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U.S.A.
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MAY - 4 2010

Contact Person:
Darlene Crockett-Billig
President
Experien Group, LLC
155-A Moffett Park Drive, Suite 210
Sunnyvale, CA 94089-1330
U.S.A.
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Email: dcb@experiengroup.com

Date Prepared:
April 12, 2010

Classification:
21 CFR§878.4810, Class II
21 CFR§886.4390, Class II

Product Code:
GEX, HQF

Trade Name:
PASCAL® Streamline™ Photocoagulator

Generic/Common Name:
Laser instrument, surgical, powered
Laser, ophthalmic

Predicate Device:
PASCAL Streamline Photocoagulator (K092621)

SECTION 6
510(k) SUMMARY

Intended Use
The PASCAL Streamline Photocoagulator indications for use are the following:

Intended for use in the treatment of ocular pathology in the posterior segment. Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

- proliferative and nonproliferative diabetic retinopathy
- macular edema
- choroidal neovascularization
- branch and central retinal vein occlusion
- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments

Intended for use in the treatment of ocular pathology in the anterior segment including:

- iridotomy
- trabeculoplasty

Product Description
The PASCAL Streamline Photocoagulator is an integrated system comprising of solid state aiming and treatment lasers, control electronics, graphical user interface, slit lamp and table. It is intended for use in the treatment of ocular pathology in both the posterior and anterior segments.

Substantial Equivalence
The modified PASCAL Streamline Photocoagulator is substantially equivalent to the predicate device with regard to function, intended use and performance. Any differences in the technological characteristics between the two devices do not raise any new issues of safety or efficacy. Thus, the modified PASCAL Streamline Photocoagulator is substantially equivalent to the predicate device.

Testing in Support of Substantial Equivalence Determination
All necessary bench testing was conducted on the modified PASCAL Streamline Photocoagulator to support a determination of substantial equivalence to the predicate device.

Summary
The PASCAL Streamline Photocoagulator is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAY - 4 2010

OptiMedica Corporation
% Experien Group, LLC
Ms. Darlene Crockett-Billig
President
155-A Moffett Park Drive, Suite 210
Sunnyvale, California 94089-1330

Re: K100019
Trade/Device Name: PASCAL® Streamline™ Photocoagulator
Regulation Number: 21 CFR 886.4390
Regulation Name: Opthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: April 12, 2010
Received: April 13, 2010

Dear Ms. Crockett-Billig:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100019

Device Name: PASCAL Streamline Photocoagulator

Indications for Use:

The PASCAL Streamline Photocoagulator indications for use are the following:

Intended for use in the treatment of ocular pathology in the posterior segment. Retinal photocoagulation, panretinal photocoagulation, focal photocoagulation and grid photocoagulation for vascular and structural abnormalities of the retina and choroid including:

- proliferative and nonproliferative diabetic retinopathy
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- choroidal neovascularization
- branch and central retinal vein occlusion
- age-related macular degeneration
- lattice degeneration
- retinal tears and detachments

Intended for use in the treatment of ocular pathology in the anterior segment including:

- iridotomy
- trabeculoplasty

Prescription Use _X_ and/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for MXA
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100019