SECTION 6
510(k) SUMMARY (CONT.)

510(k) Notification K 092621

GENERAL INFORMATION

Applicant:
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U.S.A.
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SEP 25 2009

Contact Person:
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President
Experien Group
155-A Moffett Park Drive, Suite 210
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U.S.A.
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Email: dcb@experiengroup.com

Date Prepared:
August 25, 2009

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 Photocoagulator (K091666)

SECTION 6
510(k) SUMMARY (CONT.)

Intended Use
Intended for use in the treatment of ocular pathology in both the posterior and anterior segments.

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
- iridotomy, iridectomy and trabeculoplasty in angle closure and open angle glaucoma.

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 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 proposed 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 proposed 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

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

SEP 25 2009

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

Re: K092621
Trade/Device Name: PASCAL Streamline Photocoagulator
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: HQF
Dated: August 25, 2009
Received: August 26, 2009

Dear Ms. Crocket-Bilig:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR 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): K092621

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 both the posterior and anterior segments.

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
- iridotomy, iridectomy and trabeculoplasty in angle closure and open angle glaucoma.

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 Ogden for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092621