K08 3616

JUN 12 2009

Section 5 – 510(k) Summary

I. General Information

Submitter:	PathoLase, Inc. 275 Airpark Boulevard Suite 500 Chico, CA 95973 Tel: 530-809-3800
Contact Person:	John Strisower Chairman & Chief Executive, PathoLase, Inc.
Summary Preparation Date:	May 6, 2009

II. Names

Device Names:	PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers (and delivery device accessories)
Primary Classification Names:	Laser Powered Surgical Instruments (and Accessories)

III. Predicate Devices

- Modified Lumenis VersaPulse PowerSuite Holmium (Ho:YAG) and Dual Wavelength (Ho:YAG/ Nd:YAG) Surgical Lasers and Delivery Devices with Accessories – 2100 nm & 1064 nm (K011703)
- Incisive InPulse Dental Laser – 1064 nm (K011423).

IV. Product Description

The PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers are comprised of the following main components:

- **Main console** containing the major electrical components, including:
  - Control/ Display Panel with the:
    - Keyswitch (that controls authorized access to the laser system);
    - emergency Laser Stop button;
    - Displays (laser emission indicator, average power, pulse energy, repetition rate)
    - Standby button (default mode when laser system turned on – places system into the Standby mode preventing laser emission).
    - Ready button (places system into the Ready mode allowing laser emission when the footswitch is depressed and a fiber optic is properly attached);
  - 1064 nm treatment laser (solid state Nd:YAG laser rod) with flashlamp and associated light regulation components and electronics;
  - 630 -680 nm (red) aiming beam diode laser;
  - Delivery device fiber-optic connector port;
  - Remote interlock connector (External door interlock connector);

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- Connector ports for the footswitch and power cord;
- Accessory holder (attached to the rear of the main console);

- Footswitch;
- Medical grade power cord;
- Delivery Devices for **Non-Contact and Contact with Intact Skin/Tissue**:
  - Guide Tip - **No Standoff**: Reusable, cleanable, tip is provided for **non-contact use** to direct and control the placement of the laser beam (free beam) at the treatment location. The Guide tip attaches to the end of the handpiece. The optical fiber is threaded through the handpiece and fits securely into the bore of the Guide tip;
  - Guide Tip - **With Standoff**: Reusable, cleanable, tip is provided for **minimal-contact with intact skin/ tissue** to direct and control the placement of the laser beam at the treatment location. The Guide tip attaches to the end of the handpiece. The optical fiber is threaded through the handpiece and fits securely into the bore of the Guide tip;
- Delivery Devices for **Contact with Breached Surfaces (Previously Cleared in K011423)**:
  - Optical Fibers - Reusable, cleanable, sterilizable optical fibers (range of 200 – 1000 um diameter) provided non-sterile, clean and ready for sterilization (steam autoclave).
  - Handpieces - Reusable, cleanable, sterilizable handpieces (large and small diameter shafts) provided non-sterile, clean and ready for sterilization (steam autoclave). The optical fiber is threaded through the handpiece and secured and held in place with the handpiece locking cap;
  - Handpiece Tips - Disposable single-use tips are provided in straight and curved configurations and are used to direct and control the placement of the optical fiber tip at the treatment location. The handpiece tips attach to the end of the handpiece. The optical fiber is threaded through both the handpiece and the handpiece tip;
- Accessories:
  - Safety Glasses
- Tools:
  - Optical Fiber Striper;
  - Optical Fiber Cleaver (carbide wedge, ceramic, or equivalent scribe for cleaving the optical fibers).

V. Rationale for Substantial Equivalence

The PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers share the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VI. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers are substantially equivalent to the predicate devices.

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VII. Conclusion

The PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers were found to be substantially equivalent to the predicate devices.

The PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers share identical indications for use, similar design features, and functional features with, and thus are substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PathoLase, Incorporated
A L Voss Associates
% Ms. Anne Worden
3637 Bernal Avenue
Pleasanton, California 94566

JUN 12 2009

Re: K083616
Trade/Device Name: PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for Use In General And Plastic Surgery and In Dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 6, 2009
Received: May 8, 2009

Dear Ms. Worden:

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,

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

Enclosure

Indications for Use Statement - Continued

510(k) Number (if known): K083616

Device Name: **PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers**

Indications for Use:

The PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers and the delivery accessories that are used with them are intended for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in the medical specialties of general and cosmetic dentistry, otolaryngology/ENT surgery, and dermatology & plastic surgery including:

Oropharangeal / Dental Surgery

Indicated for:

- Abscess incision and drainage
- Aphthous ulcers treatment
- Biopsies, excisional and incisional
- Crown lengthening
- Exposure of unerupted / partially erupted teeth
- Fibroma removal
- Frenectomy
- Frenotomy
- Gingival incision and excision
- Gingivectomy
- Gingivoplasty
- Hemostatis
- Implant recovery
- Lesion (tumor) removal
- Leukoplakia
- Operculectomy
- Oral papillectomy
- Pulpotomy

Prescription Use ✓ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

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Division of Surgical, Orthopedic,
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510(k) Number K083616

Indications for Use Statement - Continued

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Device Name: **PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers**

Indications for Use - Continued:

Oropharangeal / Dental Surgery - Continued

- Pulpotomy as adjunct to root canal therapy
- Removal of filling material such as gutta percha or resin as adjunct treatment during root canal re-treatment
- Selective ablation of enamel (first degree) caries removal
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket) to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss, and tooth mobility
- Tissue retraction for impressions
- Vestibuloplasty

General Surgery

Indicated for:

- Open, laparoscopic, and endoscopic general surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:
  - Cholecystectomy
  - Lymphadenectomy
  - Mastectomy
  - Partial nephrectomy
  - Hepatectomy
  - Pilonidal cystectomy
  - Pancreatectomy
  - Resection of lipoma
  - Splenectomy
  - Pelvic adhesiolysis
  - Hemorrhoidectomy
  - Removal of lesions

Prescription Use ✓ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Neil R. Ogden for mkm

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Indications for Use Statement - Continued

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Device Name: **PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers**

Indications for Use - Continued:

General Surgery - Continued

- Thyroidectomy
- Removal of polyps
- Parathyroidectomy
- Removal of tumors
- Herniorrhaphy
- Tumor biopsy
- Tonsillectomy
- Debridement of decubitus ulcers
- Appendectomy

Endonasal Surgery

Endonasal surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Lesions or tumors of the oral, nasal, glossal, pharyngeal & laryngeal tissues
- Tonsillectomy
- Adenoidectomy

Podiatry

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Matrixectomy
- Periungual and subungual warts
- Plantar warts
- Radical nail excision
- Neuromas

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Indications for Use Statement - Continued

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Indications for Use - Continued:

Dermatology and Plastic Surgery

Dermatology and plastic surgery (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Lesions of skin and subcutaneous tissue
- Telangiectasia
- Port wine lesions
- Spider veins
- Hemangiomas
- Plantar warts
- Periungual and subungual warts
- Removal of tattoos
- Debridement of decubitus ulcer
- Treatment of keloids

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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