PinPointe™

Section 5 – 510(k) Summary

OCT 15 2010

I. General Information

Submitter: PinPointe USA, Inc.
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Contact Person: John Strisower
Chief Executive Officer, PinPointe USA, Inc.

Summary Preparation Date: October 13, 2010

II. Names

Trade Name(s): PinPointe™ FootLaser™ (and delivery device accessories)

Common Name(s): Laser Powered Surgical Instruments

Primary Classification Names: Laser Powered Surgical Instruments (and Accessories) (21 CFR Part 878.4810, Product Code GEX)

III. Predicate Devices

- PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Nd:YAG Lasers (K083616)
- Incisive Family of InPulse Nd:YAG Lasers (K083215).

IV. Product Description

The PinPointe™ FootLaser™ is 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);

  - 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:
  - 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. Indications for Use

The PinPointe™ FootLaser™ 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 intraoral soft tissue dental surgery, oral maxillo-facial and cosmetic surgery, general surgery, E.N.T. surgery, podiatry, and dermatology and plastic surgery.

K093547

Podiatry

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

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

The PinPointe™ FootLaser™ is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

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

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
- Hemostasis
- Implant recovery
- Lesion (tumor) removal
- Leukoplakia
- Operculectomy
- Oral papillectomy
- Pulpotomy
- 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
  - Removal of lesions
  - Thyroidectomy
  - Removal of polyps
  - Parathyroidectomy
  - Removal of tumors

- Pilonidal cystectomy
- Pancreatectomy
- Resection of lipoma
- Splenectomy
- Pelvic adhesiolysis
- Hemorrhoidectomy
- 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

The safety and effectiveness of the PinPointe™ FootLaser™ for use for the temporary increase of clear nail in patients with onychomycosis was demonstrated in clinical studies.

VI. Summary of Technological Characteristics

The technological characteristics of the PinPointe™ FootLaser™ are identical to those of the predicate devices.

Characteristic	K093545 - PinPointe™ FootLaser™ and Delivery Devices; Incisive, Inc.			K083616 - PathoLase Family of PinPointe™ and PinPointe™ FootLaser™ Lasers; PathoLase, Inc.			K0832153 - Incisive Family of InPulse Nd:YAG Lasers; Incisive, LLC		
Wavelength	1064 nm			1064 nm			1064 nm		
Aiming Beam	630-680 nm (≤ 2.5 mW)			630-680 nm (≤ 2.5 mW)			630-680 nm (≤ 2.5 mW)		
Model	6 W	30 W	100 W	6 W	30 W	100 W	6 W	30 W	100 W
Energy Per Pulse (mJ)	20-200	20-1000	20 - 3500	20-200	20-1000	20 - 3500	20-200	20-1000	20 - 3500
Power (Watts)	≤ 6	≤ 30	≤ 100	≤ 6	≤ 30	≤ 100	≤ 6	≤ 30	≤ 100
Pulse Duration (μsec)	100 - 700	350 – 3000	350 - 3000	100 - 3000			100 - 700	350 – 3000	350 - 3000
Output Mode	Pulsed, Multi-Mode			Pulsed, Multi-Mode			Pulsed, Multi-Mode		
Repetition Rate	5 – 100 Hz			5 – 100 Hz			5-100 Hz		
Laser Media	Flashlamp-Pumped Solid State Laser Rod			Flashlamp-Pumped Solid State Laser Rod			Flashlamp-Pumped Solid State Laser Rod		
User Interface	Push-button control panel			LCD Color touch screen			Push-button control panel		
Laser Activation	Footswitch			Footswitch			Footswitch		
Delivery Devices • How supplied	• Non-sterile, reusable, cleanable, sterilizable			• Non-sterile, reusable, cleanable, sterilizable			• Non-sterile, reusable, cleanable, sterilizable		
System Dimensions	32" x 13" x 14" (H x W x D)			32" x 13" x 14" (H x W x D)			32" x 13" x 14" (H x W x D)		
System Weight	17.2 kg (38 lbs)			17.2 kg (38 lbs)			17.2 kg (38 lbs)		
Electrical Reqs.	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz			90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz			90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz		

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Clinical study demonstrated the safety and effectiveness of the PinPointe™ FootLaser™ for use for the temporary increase of clear nail at 6 and 12 months following treatment in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

VIII. Safety and Effectiveness Information

The review of the indications for use, technical characteristics, and clinical study results provided demonstrates that the PinPointe™ FootLaser™ is substantially equivalent to the predicate devices and is safe and effective for use for the temporary increase of clear nail at 6 and 12 months following treatment in patients with onychomycosis.

IX. Conclusion

The PinPointe™ FootLaser™ was found to be substantially equivalent to the predicate devices.

The PinPointe™ FootLaser™ 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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

PinPointe USA, Inc.
% Ms. Anne Worden
Regulatory Consultant
3637 Bernal Avenue
Pleasanton, California 94566

Re: K093547
Trade/Device Name: PinPointe FootLaser and Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: PDZ, GEX
Dated: October 13, 2010
Received: October 14, 2010

Dear Ms. Worden:

This letter corrects our substantially equivalent letter of October 15, 2010.

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" (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, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

OCT 15 2010

510(k) Number (if known): K093547

Device Name: PinPointe™ FootLaser™

Indications for Use:

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

The PinPointe™ FootLaser™ is indicated for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.).

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

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

510(k) Number K093547

Indications for Use Statement - Continued

510(k) Number (if known): K093547

Device Name: PinPointe™ FootLaser™

Indications for Use - Continued:

Dermatology and Plastic Surgery

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

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- Treatment of keloids

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

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Nick R. Pyatt for mxm

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093547

Indications for Use Statement - Continued

510(k) Number (if known): K093547

Device Name: PinPointe™ FootLaser™

Indications for Use - Continued:

Oropharangeal / Dental Surgery - Continued

Indicated for:

- Hemostasis
- Implant recovery
- Lesion (tumor) removal
- Leukoplakia
- Operculectomy
- Oral papillectomy
- Pulpotomy
- 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

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

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510(k) Number K093547

Indications for Use Statement - Continued

510(k) Number (if known): K093547

Device Name: PinPointe™ FootLaser™

Indications for Use - Continued:

General Surgery - Continued

Indicated for:

- Pilonidal cystectomy
- Pancreatectomy
- Resection of lipoma
- Splenectomy
- Pelvic adhesiolysis
- Hemorrhoidectomy
- Removal of lesions
- 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:

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