K 062048

Section 5 – 510(k) Summary or ~~510(k) Statement~~

SEP - 7 2006

I. General Information

Submitter:	Aesthera Corporation 6634 Owens Drive Pleasanton, CA 94588 USA
Contact Person:	Robert Anderson Chief Technical Officer
Summary Preparation Date:	July 18, 2006

II. Names

Device Names:	Aesthera Photopneumatic™ (PPx™) System
Primary Classification Names:	Accessory for, Laser Powered Surgical Instruments

III. Predicate Devices

- Aesthera AIP Intense Pulsed Light System (K041554);
- Radiancy Acne System with ClearTouch Light Unit Assembly (K051268);
- Radiancy Skin Station with Modified Light Unit Assembly for Psoriasis System (K052442);
- Radiancy ClearTouch Lite Acne Clearance System (K060411);
- Palomar LuxV Pulsed Light Handpiece for StarLux Systems (K040081);
- Palomar StarLux Pulsed Light System (K041086);
- Novalis Clareon & Solarus Pulsed Light Systems w/ AR Handpiece (K043319)

IV. Product Description

The Aesthera Photopneumatic™ (PPx™) System is comprised of the following main components:

- Main console
- PPx™ Treatment Handpiece
- Optional coolant accessory – cryogenic, water, or air spray for cooling the handpiece tip; and
- Treatment Footswitch.

The Aesthera Photopneumatic™ (PPx™) System (with treatment handpiece) is a portable tabletop system used to deliver intense pulsed light to the patient treatment site via a delivery handpiece utilizing Photopneumatic technology. Intense pulsed light is emitted through the IntelliTip™ only when the tip is sealed against the selected patient treatment site. All emitted light is contained within the IntelliTip™ during treatment. The handpiece is uniquely designed to promote increased ergonomics with all user interface and controls located on the handpiece.

V. Indications for Use

The Aesthera Photopneumatic™ (PPx™) System is intended for:

- The treatment of benign vascular and pigmented lesions:
- Permanent hair reduction;
- The treatment of mild to moderate acne, including pustular acne, comedonal acne, and mild to moderate inflammatory acne (acne vulgaris).

The Aesthera Photopneumatic™ (PPx™) System is intended for use on all skin types (Fitzpatrick skin types I-VI).

VI. Rationale for Substantial Equivalence

The Aesthera Photopneumatic™ (PPx™) System shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics and the published medical literature provided demonstrates that the Aesthera Photopneumatic™ (PPx™) System is substantially equivalent to the predicate devices. Clinical data demonstrating the safety and effectiveness of the Aesthera Photopneumatic™ (PPx™) System for the treatment of mild to severe acne, including pustular acne, comedonal acne, and mild to moderate inflammatory acne (acne vulgaris) was provided.

VIII. Conclusion

The Aesthera Photopneumatic™ (PPx™) System was found to be substantially equivalent to the predicate devices.

The Aesthera Photopneumatic™ (PPx™) System shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2006

Aesthera Corporation
% AL Voss Associates
Ms. Anne Worden
Regulatory Consultant
3637 Bernal Avenue
Pleasanton, California 94566

Re: K062048
Trade/Device Name: Aesthera Photopneumatic™ (PPx™) System
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: July 18, 2006
Received: July 20, 2006

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 such 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.

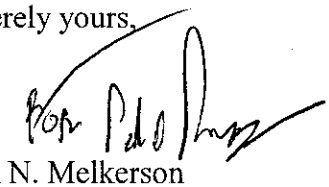
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): **K062048**

Device Name: Aesthera Photopneumatic™ (PPx™) System

Indications for Use:

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- The treatment of benign vascular and pigmented lesions;
- Permanent hair reduction;
- The treatment of mild to moderate acne, including pustular acne, comedonal acne, and mild to moderate inflammatory acne (acne vulgaris).

The Aesthera Photopneumatic™ (PPx™) System is intended for use on all skin types (Fitzpatrick skin types I-VI).

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062048