K083730

Section 5

510(k) Summary

JAN - 9 2009

General Information

Classification	Class II
Trade Name	Isolaz™ Intense Pulsed Light System
Submitter	Aesthera 6634 Owens Drive Pleasanton, CA 94588 Tel: 877 275 4779 Fax: 925 737 2197
Contact	Pamela M. Buckman, MSN Consultant Buckman Company, Inc. 1070 Concord Ave., Suite 230 Concord, CA 94520 Tel: 925 980 7007 Fax: 925 356 2654

Intended Use

The Isolaz™ is intended to treat benign vascular and pigmented lesions, permanent hair reduction, mild to moderate acne, including pustular acne, comedonal acne and mild to moderate inflammatory acne (acne vulgaris) in all skin types (Fitzpatrick I-VI).

Predicate Devices

K062048 Aesthera Photopneumatic PPx™ System

Device Description

The Isolaz™ System is a portable tabletop system used to deliver non-coherent 400-1200nm, 530-12000nm and 580-1200nm intense pulsed light via a delivery handpiece utilizing photpneumatic technology. The system consists of a main console, a treatment handpiece and a footswitch. The desired power and delivery time are set manually by the operator.

Materials

All materials used in the manufacture of the Isolaz™ are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. The results showed the system met specification.

Summary of Substantial Equivalence

The Isolaz™ System is equivalent to the predicate product. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2009

Aesthera Corporation
% Buckman Company, Inc.
Ms. Pamela M. Buckman, MSN
President
1070 Concord Avenue, Suite 230
Concord, California 94520

Re: K083730
Trade/Device Name: Isolaz™ 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: December 15, 2008
Received: December 16, 2008

Dear Ms. Buckman:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number: ~~Pending~~ K083730

Device Name: Isolaz™ System

Indications for Use: The Isolaz™ System is designed to treat benign vascular and pigmented lesions, permanent hair reduction, mild to moderate acne, including pustular acne, comedonal acne and mild to moderate inflammatory acne (acne vulgaris) in all skin types (Fitzpatrick I-VI).

X		
Prescription Use (Per 21 CFR 801 Subpart D)	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 K083730