K 062312

510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

OCT 16 2006

Submitter:

General Project, S.r.l.
Via della Gora 13/1-15/19
50025 Montespertoli, Florence
Italy

Contact Person:

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Summary Preparation Date: July23, 2006

2. Names

Proprietary Name: Axiom Intense Pulsed Light System
Common Name: IPL System
Classification Name: Laser surgical instrument for use in General and Plastic Surgery and in Dermatology.
Product Code: GEX, Panel 79

3. Legally Marketed Predicate Devices

General Project's Flash1 (K022583)
General Project's Med FlashII (K051508)
Radiancy's SpaTouch (K020856)
Lumenis' IPL Quantum SR (K020839)
Novalis Medical's Clareon Pulsed Light System (K043319)
Cynosure's Photosilk Plus (K041095).

The AXIOM Intense Pulsed Light System is substantially equivalent to the Flash 1 and the MedFlash II manufactured by General Project, Montespertoli, Florence, Italy. The AXIOM Intense Pulse Light system shares the same indications for use and the same or similar technological characteristics including: controls and displays and light source.

4. Device Description

The Axiom Intense Pulsed Light System is a medical device emitting light radiation in the range from 590 nm to 1200 nm. The system is based on a quick power discharge of capacitors in a Xenon lamp, mounted on a handpiece. This generates a rapid and Intense Pulsed Light. The four principal parts of the Axiom system include the charge system of the capacitors, electronic control system, control panel, and a handpiece with exchangeable lamp box

5. Intended Use

The Axiom Intense Pulsed Light System is intended for treatment of mild to moderate inflammatory acne (acne vulgaris), removal of unwanted hair from all skin types and to effect stable, long-term or permanent hair reduction. The Axiom is also indicated for treatment of benign pigmented epidermal and cutaneous lesions including warts, scars, striae, lentigines, nevi, melasma and cafè-au-lait

6. Performance Data

No performance data is required for this Class II device nor requested by the Food and drug Administration (Office of Device Evaluation). A database search has been conducted to evaluate any adverse effects of the device that is currently marketed.

No data submitted for section 807.92 6[(b)(1)(2)(3c). See attached documentation of adverse effects.]

Conclusion:

The AXIOM Intense Pulsed Light System is substantially equivalent to the Flash 1 and Med Flash II. The AXIOM Intense Pulse Light System shares the same indications for use and technological characteristics as the predicate Intense Pulsed Light Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

General Project, S.r.l
% CDI Regulatory Consultants
Ms. Cornelia Damsky
56 Westcott Road
Stamford, Connecticut 06902

Re: K062312
Trade/Device Name: **AXIOM Intense Pulsed Light 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: August 4, 2006
Received: August 9, 2006

Dear Ms. Damsky:

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

510(k) Number (if known): **K062312**

Device Name: **AXIOM Intense Pulsed Light System**

Indications for Use:

The Axiom Intense Pulsed Light System is a medical device emitting light radiation in the range from 590 nm to 1200 nm. It is intended for use in:

- Removal of unwanted hair from all skin types and to effect stable long-term or permanent, hair reduction
- Treatment of mild to moderate inflammatory acne (acne vulgaris)
- Treatment of benign pigmented epidermal and cutaneous lesions including warts, scars, striae, lentigines, nevi, melasma and café-au-lait.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062312