K 072344

510(k) SUMMARY

Submitter:	Bios Italia s.r.l. Via Guido Rossa, 10/12 20090 Vimodrone (MI) – Italy
Contact:	Aldo Casalino
Date Summary Prepared:	June 27, 2007
Device Trade Name:	APL MEDICAL SYSTEM
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser GEX and FTC 21 CFR 878.4810 and 21 CFR 878.4630
Equivalent Device:	MSq(M2) LTD – Lovely System (k042000 and k033946)
Device Description:	The portable device APL MEDICAL SYSTEM, is a multi-laser and pulsed light system, designated to act on the most diffused imperfections of the skin and body. The equipmentm is conceived as an expandable system for the field of aesthetic medicine, composed of a modular platform, containing the entire electronics of the system and the cooling circuit, and a series of interchangeable hand pieces to be connected on the platform, finalized to treat specific groups of imperfections. A rapid connection enables the quick and easy replacement of the various hand pieces that can be mounted on the modular platform. The following hand pieces are available: 1) Hand piece Pulsed Light. With the use of this hand piece the removal of unwanted hair is extremely quick and efficient, as it is possible to treat large areas (up to 9 cm2) using a single pulse or "burst" mode This system is effective on varius skin types. On this hand piece it is possible to change easily the guide light, equipped with a specific light filter and to use thus that one most adequate for the individual photo type. Furthermore, it is

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possible to conduct a combination of methods to attenuate facial skin imperfections related to small perorbital and labial wrinkles. With the use of guide lights within the spectrum 300-380 nm it is possible to treat psoriasis and vitiligo disease with a specific therapy. This technique has the advantage of acting directly on the concerned area while respecting the surrounding tissues.

2) Hand piece Nd:Yag Laser at 1064nm, long pulse (ms). With this laser it is possible to treat teleangectasies easyly and quickly with optimal results and without leaving a cicatrix. Furthermore, it is possible to hair removal on small areas with "difficult" skin and hairs.

3) Hand piece Nd:Yag Laser 1064 and 532 nm Qs (Q-switched), short pulse (ns). This laser is able to selectively destroy melanosomes through cell lysis. The Qs laser is ideal for the treatment of pigmentated lesions and in general for all superficial pigmentations, since its wavelength is well absorbed by the melanin as well as by the haemoglobin. Furthermore, the pulse width makes this type of laser selective with regards to melanosomes –i.e. benign freckles, ephelis, café-au-lait stains, nervus pilus, seborrheic keratosis and skin chloasm, and tattoos. Fin and superficial vessels are better treated with the Nd:Yag laser 532 nm Qs which causes less pain than other laser types, completing the treatment which may effect the Nd:Yag laser, long pulse.

4) Hand piece Erbium Laser at 2.940 nm. Due to the high power and the exclusive guide light, the use of this laser results in the ablation process which is a delicate and uniform exfoliation of the atrophic superficial (5 micron) layer of the skin.

Intended Use:

The APL MEDICAL SYSTEM is indicate for: removal of unwanted hair and to effect stable long-term or permanent hair reduction; laser skin procedures for the treatment of acne scars and wrinkles; incision, excision, ablation, vaporization of soft tissue; non-ablative treatment of facial wrinkles, such as, but not limited to periocular wrinkles and perioral wrinkles; removal of tattoos and blemishes of the skin, the treatment of various pigmentation lesions, treatment of capillaries, teleangiectasies and vascular lesions, the treatment of vitiligo and psoriasis.

Rationale for Substancial Equivalence:	The product specification, functionality, indication for use, and treatment parameters of the APL MEDICAL SYSTEM are the same or very similar to the legally marketed laser MSq(M2) LTD – Lovely System Model: Lovely II Harmony. Both systems have the same indication for use. Both systems comprise a flashlamp pumped laser rod (Nd:YAG) generating light at a wavelength of 1064 nm, which is subsequently delivered to the patient via an optical fiber delivery system, and focusing handpiece. The APL MEDICAL SYSTEM output characteristics (including pulse duration and fluence) are identical, or very similar, to those of the predicate device. Both lasers utilize class IIIA aiming beams. Both lasers are microprocessor controlled devices. Both systems utilize an internal closed loop water-air heath exchanger circuit for optimal thermal control of laser cavity The risks and benefits for the APL MEDICAL SYSTEM are comparable to those for the predicate device. Therefore, the introduction of this laser should not raise new questions of Safety and Effectiveness .

Non-Clinical Performance Data: None

Clinical Performance Data: None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Bios Italia s.r.
% Mr. Aldo Casalino
General Manager
Via Guido Rossa, 10/12
Vinodrone (Milan) MI I-20090
Italy

Re: K072344
Trade/Device Name: APL Medical 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, FTC
Dated: November 8, 2007
Received: November 27, 2007

Dear Mr. Casalino:

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

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K072344

Device Name: APL MEDICAL SYSTEM

Sponsor Name: Bios Italia s.r.l.

Indication for Use:

The APL MEDICAL SYSTEM is a modular multi-laser and multi-use device and are intended for use in aesthetic, cosmetic, and surgical applications.

It is used to treat common imperfections and lesions of skin and body , including:

1. The removal of unwanted hair and to effect stable long-term or permanent hair reduction
2. Laser skin treatment procedures for the treatment of:
   - Acne scars
   - Wrinkles
3. Incision, excision, ablation, vaporization of soft tissue
4. The non-ablative treatment of facial wrinkles, such as, but not limited to:
   - Periocular wrinkles
   - Perioral wrinkles
5. Removal of tattoos and blemishes of the skin, the treatment of various pigmentation lesions
6. Treatment of capillaries, teleangiectasies and vascular lesions
7. Treatment of vitiligo and psoriasis

The equipment should only be used under medical supervision.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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Prescription Use ☒
Over-The-Counter Use ☐