K080374

510(k) SUMMARY

MAY 15 2008

Submitter:	Bios Italia s.r.l. Via Guido Rossa, 10/12 20090 Vimodrone (MI) – Italy
Contact:	Aldo Casalino
Date Summary Prepared:	January 21, 2008 (revised April 17, 2008)
Device Trade Name:	BIOSYAG 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:	BIOS ITALIA S.R.L. • Bios Yag 50 Med - 510(k) n°: K043521 • APL Medical System - 510(k) n°: K072344
Device Description:	The BIOSYAG MEDICAL SYSTEM is a modular multi-laser and multi-use device for the cosmetic treatment of face and body. It is used to treat common imperfections and lesions of skin and body. The BIOSYAG MEDICAL SYSTEM includes the following light sources: o Nd:YAG 50 J (internal laser source) o Nd:YAG Q-switched (handpiece) o Er:YAG (handpiece) o Pulsed Light source The handpiece is the part that the user grips to carry out the laser treatment and consists of a main body and a removable end section that defines the size of the work beam. At the resonator lead-in an appropriately dimensioned fibre is connected with a focussing device fitted on the end, used to treat the patient.

The system is supplied with a set of adapters to be able to use different work beam dimensions.
The cooling section consists of a deionised water/air heat exchanger.
The foreseen operating cycle is intermittent, operating at maximum power for 10 minutes, followed by a 5 minute pause.
The management of the source and the work parameters is by means of a control panel with a liquid crystal colour screen and touch screen functions.

Intended Use:

The Intended Uses for the BIOSYAG MEDICAL SYSTEM are the following:

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, telcangiectasies and vascular lesions.
7. Treatment of vitiligo and psoriasis.

The correlation between type of light source, wavelength, and intended use is outlined in the table displayed on the following table.

Correlation between BIOSYAG Light Sources, wavelength and Intended Uses

Light Source	Wavelength (nm)	Specific Intended Use
ND:YAG 50J (internal source)	1064	- Removal of tattoos and blemishes of the skin, the treatment of various pigmentation lesions - The non-ablative treatment of facial wrinkles.
ND:YAG Q-SWITCHED (handpiece)	1064+532	- Laser skin treatment procedures for the treatment of: acne scars; wrinkles - The removal of unwanted hair and to effect stable long term or permanent hair reduction,
ER:YAG (handpiece)	2940	- Incision, excision, ablation, vaporization of soft tissue, - The non-ablative treatment of facial wrinkles. - Treatment of capillaries, teleangiectasies and vascular lesions,
Pulsed Light	300- 1000	- Treatment of vitiligo and psoriasis (300-380 nm). - The removal of unwanted hair and to effect stable long term or permanent hair reduction (420-950 nm),

Rationale for Substantial 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 Bios Italia srl – Bios Yag 50 Med and APL Medical System.

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 BIOSYAG 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 BIOSYAG 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
Rockville MD 20850

MAY 15 2008

Bios S.R.L.e, Inc.
% Onde Consulting, LLC
Alessandro Franchi
4235 E. Broadway
Long Beach, California 90803

Re: K080374
Trade/Device Name: BIOSYAG MEDICAL SYSTEM
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical insgrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 20, 2008
Received: March 24, 2008

Dear Alessandro Franchi:

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): __ K080374_____

Device Name: BIOSYAG MEDICAL SYSTEM

Sponsor Name: Bios Italia s.r.l.

Indication for Use:

The BIOSYAG MEDICAL SYSTEM is a modular multi-laser and multi-use device for the cosmetic treatment of face and body. 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, vaporisation 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 correlation between type of light source, wavelength, and intended use is outlined in the table displayed on the following page.

The equipment should only be used under medical supervision.

Do Not Write Below This Line – Continue on Another Page if Needed

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mm

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

Prescription Use ☒

Over-The-Counter Use ☐

510(k) Number K080374

Correlation between BIOSYAG Light Sources, wavelength and Intended Uses

Light Source	Wavelength (nm)	Specific Intended Use
ND:YAG 50J (internal source)	1064	- Removal of tattoos and blemishes of the skin, the treatment of various pigmentation lesions - The non-ablative treatment of facial wrinkles.
ND:YAG Q-SWITCHED (handpiece)	1064+532	- Laser skin treatment procedures for the treatment of: acne scars; wrinkles - The removal of unwanted hair and to effect stable long term or permanent hair reduction,
ER:YAG (handpiece)	2940	- Incision, excision, ablation, vaporisation of soft tissue, - The non-ablative treatment of facial wrinkles. - Treatment of capillaries, teleangiectasies and vascular lesions,
Pulsed Light	300- 1000	- Treatment of vitiligo and psoriasis (300-380 nm). - The removal of unwanted hair and to effect stable long term or permanent hair reduction (420-950 nm),

Neil R Ogden for mkm

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

510(k) Number K080374