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(S001)

# 510(k) SUMMARY

MAR 2 4 2005

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| Submitter: | Bios s.r.l.<br>Via Pisa, 61<br>20093 Cologno Monzese (MI) – Italy |
| Contact: | Aldo Casalino |
| Date Summary Prepared: | September 30, 2004 |
| Device Trade Name: | BIOSYAG 50 Med |
| Common Name: | Medical Laser System |
| Classification Name: | Instrument, surgical, powered, laser<br>79 – GEX<br>21 CFR 878.4810 |
| Equivalent Device: | Cynosure Smartepil (K020107) |
| Device Description: | The BIOSYAG 50 Med laser is a pulse Nd: YAG laser utilizing the Nd:YAG crystal as the lasing medium. It is a pulsed laser with wavelength of 1064 nm.<br>Within the system an optical cavity contains the Nd:YAG crystal which is activated by means of the use of flash lamps. After the cavity a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly.<br>The combined therapeutic and aiming beam are guided down an optical fiber delivery system to a focusing handpiece. The laser is used in non-contact mode.<br>The BIOSYAG 50 Med laser is composed by 5 major subsystems:<br>a) A high voltage power supply which converts and rectifies the a.c. main current to provide regulate power for the flashlamp simmer current and main triggering pulse.<br>b) A cooling system consisting of an internal water flow circuit with water-to-air hath exchanger. |

c) An optical delivery system, interfacing the energy from the laser to patient via an optical fiber and focusing handpiece.
d) A microprocessor based controller which regulates the functions of the laser and allows parameter selection by the user.

Intended Use:

The BIOSYAG 50 Med laser is indicated for benign vascular lesions and hair removal.

Rationale for Substantial Equivalence:

The product specification, functionality, indication for use, and treatment parameters of the The BIOSYAG 50 Med laser are the same or very similar to the legally marketed laser Cynosure Smartepil.

Both equipments have the same indication for use.

Both system 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.

BIOSYAG 50 Med output characteristics (including pulse duration and fluence) are identical, or very similar, to those of predicate device.

Both lasers utilize class IIIA aiming beam.

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 risk and benefits for the BIOSYAG 50 Med are comparable to the predicate device, it is therefore believed that there are no new questions of Safety and Effectiveness raised by the introduction of this device.

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

MAR 2 4 2005

Bios s.r.l.
c/o Mr. Allessandro Franchi
Quality Management & Services
16 Indian Spring Drive
Silver Spring, Maryland 20901

Re: K043521
Trade/Device Name: BIOSYAG 50 Med
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: March 11, 2005
Received: March 14, 2005

Dear Mr. 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 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting 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): K043521/S001

Device Name: BIOSYAG 50 Med

Sponsor Name: Bios s.r.l.

Indication for Use:

**The BIOSYAG 50 Med laser is indicated for treatment of benign vascular lesions and hair reduction.**

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)

Prescription Use ☒
Over-The-Counter Use ☐

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
K043521