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4. 510(K) SUMMARY

This 510 (k) summary of safety and effectiveness for the Focus Medical NaturaLase 980 Laser System is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510 (k) summary.

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Applicant:	Focus Medical 23 Francis J. Clarke Circle Bethel, CT 06801 203-730-8885
Manufacturer:	Focus Medical 23 Francis J. Clarke Circle Bethel, CT 06801
Contact Person:	Mr. John B. Lee, Jr. President Focus Medical
Name of the Device:	NaturaLase 980 Laser System
Predicate Devices:	This is device is substantially equivalent to: Osyris Pharaon Lipo (K073617) PhotoMedex LaserPro (K082721)
Device Description:	The NaturaLase 980 Laser System is a diode laser system with 980 nm wavelength light.
Indications for Use:	NaturaLase 980 Laser System is intended for laser assisted lipolysis. The NaturaLase 980 Laser System is intended for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, plastic surgery, dentistry, gastroenterology, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, ophthalmology, orthopedics, pulmonology, thoracic surgery arthroscopy and podiatry.
Conclusion:	The specifications, indications for use and performance of the NaturaLase 980 Laser System is substantially equivalent to the legally marketed predicate devices. It raises no new issues of safety and effectiveness and should be approved for marketing under the general controls provisions of the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Focus Medical, LLC
% Mr. John B. Lee, Jr.
President
23 Francis J. Clarke Circle
Bethel, Connecticut 08801

AUG 1 8 2010

Re: K101152
Trade/Device Name: NaturaLase 980 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, ORK
Dated: July 26, 2010
Received: July 27, 2010

Dear Mr. Lee:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Peter Pitts D.P.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. INDICATIONS FOR USE STATEMENT

K101152

510(k) Number: K101152

Device Name: NaturaLase 980 Laser System

Indications For Use:

NaturaLase 980 Laser System is intended for laser assisted lipolysis. The NaturaLase 980 Laser System is intended for surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, plastic surgery, dentistry, gastroenterology, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, ophthalmology, orthopedics, pulmonology, thoracic surgery arthroscopy and podiatry.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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) The

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101152