DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 1, 2015

Focus Medical, LLC
Michail M. Pankratov, MD, PhD
MMP Medical Associates LLC
16 Appleton Street
Waltham, Massachusetts 02453

Re: K151473
Trade/Device Name: NaturaLase PiQo4 - NaturaLase Nd:Y AG 1064 Q-switched Laser with 532 nm accessory and Pulse Slicing Module
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
Dated: July 8, 2015
Received: July 10, 2015

Dear Dr. Pankratov:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151473

Device Name
NaturaLase PiQo4 - NaturaLase Nd:Y AG 1064 Q-switched Laser with 532 nm accessory and Pulse Slicing Module

Indications for Use *(Describe)*

NaturaLase PiQo4 – The NaturaLase Nd:YAG 1064 Q-switched Laser with 532 nm accessory and Pulse Slicing Module –is indicated for use in aesthetic applications for the following at the specified wavelength:

532 nm - Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.

1064 nm - Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat tattoo colors: black, brown, green, blue and purple.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

As required by section 21 CFR 807.92

I. General Information

Applicant: Focus Medical, LLC
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TEL: 203-730-8885
FAX: 203-730-8851

Contact Person: Michail M. Pankratov, MD, PhD
MMP Regulatory Consultants, LLC
16 Appleton Street
Waltham, MA 02453
TEL: 617-480-4543
clregconsult@aol.com

Preparation Date: July 28, 2015

II. Device Information

Trade Name:	NaturaLase PiQo4 - NaturaLase Nd:YAG 1064 Q-Switched Laser with 532 KTP Optics and Pulse Slicing Module
Common/Usual Name:	NaturaLase Nd:YAG 1064 QS Laser
Classification:	Class II
Regulation Number:	878.4810
Product Code:	GEX
Classification Name:	Powered Laser Surgical Instrument
Review Panel:	General & Plastic Surgery
Predicate Devices:	K142372 – PicoWay Laser System, Candela Corp.

III. Device Description:

The NaturaLase PiQo4 laser is a Nd:YAG 1064 Q-Switched laser with 532 KTP Optics and Pulse Slicing Module. The 532 KTP Optics is available to convert the basic 1064 nm wavelength to 532 nm and the pulse slicing electro-optics allows diverting the leading and trailing portions of the laser pulse away from the delivery system for the purpose of shortening the pulse duration without reducing the peak power.

The NaturaLase PiQo4 laser offers fast and efficient treatment of tattoos and benign pigmented lesions removal through a variety of spot sizes, fluences and repetition rates. The laser energy is delivered via an articulated arm with interchangeable hand-pieces. A liquid crystal display (LCD) provides visual feedback of control settings and operating parameters. The mechanism of action for tattoo or pigmented lesion removal lies in delivering laser energy at very high peak power.

IV. Indication for Use:

NaturaLase PiQo4 – The NaturaLase Nd:YAG 1064 Q-switched Laser with 532 KTP Optics and Pulse Slicing Module – is indicated for use in aesthetic applications at the specified wavelength:

532 nm – removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.

1064 nm – Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat tattoo colors: black, brown, green, blue and purple

V. Technological Characteristics:

The NaturaLase PiQo4 laser has the same intended use and similar indications for use, technological characteristics and operating principles as the Candela PicoWay Laser System (K142372). The NaturaLase PiQo4 laser design and components are very similar to those of the predicate devices. They all have treatment handpieces connected to the articulated arm that is connected to the main console where the user interface is located. They all allow the spot size to be adjusted with the handpiece depending on the application. They all provide an aiming beam to assist in delivery of the therapeutic energy. Differences between the NaturaLase PiQo4 laser and predicate device in specific maximum energy levels and fluence delivered do not raise any new safety or effectiveness issues because the NaturaLase PiQo4 laser parameters fall within the range of parameters delivered by the predicate device.

VI. Testing Performance

All performance testing demonstrated that the NaturaLase PiQo4 laser performs according to specifications and functions as intended.

Electrical safety and electromagnetic compatibility (EMC) testing for the NaturaLase PiQo4 laser system was conducted by an independent laboratory in accordance with IEC 60601-1, Medical electrical equipment, part 1: general requirements for basic safety and essential performance. The NaturaLase PiQo4 laser was determined to be in conformance with applicable IEC standards (IEC 62366, 60601-1, 60601-1-6, 60601-2-22, and IEC 60825-1). The

biocompatibility of the NaruraLase PiQo4 laser is consistent with the ISO 10993. Software verification and validation testing results are acceptable for software release.

VII. Summary of Substantial Equivalence

Review of the technological characteristics for the primary predicate device and the PiQo4 Laser shows close similarity in parameters principally responsible for generating tissue effects.

	NaturaLase PiQo4 Laser (Focus Medical)		**PicoWay (Candela, Corp)**	
Wavelength	**1064 nm**	**532 nm**	**1064 nm**	**532 nm**
Pulse Duration	500 ps	500 ps	450 ps	400 ps
Pulse Energy	400 mJ	200 mJ	400 mJ	200 mJ
Pulse Fluence	1.4 J/cm2 @ 6 mm spot	1.4 J/cm2 @ 4 mm spot	1.4 J/cm2 @ 6 mm spot	1.4 J/cm2 @ 4 mm spot
Peak Power	800 MW	400 MW	889 MW	500 MW
Peak Irradiance	2.8GW/cm2 @ 6 mm spot	2.8GW/cm2 @ 4 mm spot	3.1GW/cm2 @ 6 mm spot	3.5GW/cm2 @ 4 mm spot

The NaturaLase PiQo4 laser has the same intended use as the predicate device with similar indications for use. It presents similar technological characteristics as the predicate device including the laser type, wavelengths, device design, pulse width, frequency, spot sizes and system components. Although there are some differences between the NaturaLase PiQo4 laser and its predicate device in terms of maximum pulse energy, fluence, pulse duration, etc, these differences do not present any new concerns of safety and effectiveness since the NaturaLase PiQo4 laser parameters are within the range used by the predicate devices for treatment of pigmented lesions and tattoo removal. The NaturaLase PiQo4 laser and its predicate device operate with the same mechanism of action based on selective photothermolysis and based on photothermal and significant photomechanical or acoustic effects of pigments in tattoos. Therefore, the NaturaLase PiQo4 laser has the same intended use and similar indications for use, technological characteristics, and principles of operation as predicate device. The NaturaLase PiQo4 laser is substantially equivalent to the predicate device.