K032667 1/2

JAN 2 3 2004

SECTION 9

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the Focus Medical 532 Hand Piece Adapter alone or with the Dye Pack Accessory (red or yellow) for use with the NaturaLase 1064 laser 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.

Applicant: Focus Medical

Address: 23 Francis J. Clarke Circle
Bethel, CT 06801

Manufacturer: Focus Medical

Contact Person: John B. Lee, Jr.
President
Focus Medical

Telephone: 203-730-8885

Preparation Date: August 2003
(of the Summary)

Device Name: Focus Medical 532 Hand Piece Adapter and Dye Pack Accessory (red or yellow)

Common Name: Accessories to the NaturaLase 1064 Q-Switched Laser

Classification: Laser surgical instrument for use in general and plastic surgery and in dermatology

Class II medical device
21 CFR 878.4810

Product Code: GEX
Panel: 79

Predicate devices: Continuum Medlite C3 (K011677) and C6 Q-Switched (014234) Nd:YAG lasers

Device description: The Focus Medical 532 Hand Piece Adapter and the Dye Pack Accessory are accessories to the NaturaLase 1064 Q-Switched laser. The 532 Hand Piece Adapter converts the 1064 nm laser energy of the NaturaLase to

532 nm laser energy. The Red Dye Pack Accessory converts the 532 nm laser energy to a red beam (595-660 nm) and the Yellow Dye Pack Accessory converts the 532 nm laser energy to a yellow beam (568 - 590 nm).

Indications: The **532 Hand Piece Adapter and Dye Pack Accessory (Red or Yellow)**, when attached to the NaturaLase 1064 Laser, are indicated for:

Tattoo removal
- Red inks (**532 nm Hand Piece Adapter**)
- Blue and light blue inks (**Yellow Dye Pack**)
- Green inks (**Red Dye Pack**)

Treatment of Vascular Lesions - 532 nm Hand Piece Accessory
- Port wine birthmark
- Telangiectasias
- Spider angiomas
- Cherry angiomas
- Spider nevi

Treatment of Pigmented Lesions - 532 nm Hand Piece Accessory
- Café-au-lait birthmarks
- Solar lentigines
- Senile lentigines
- Becker's nevi
- Freckles
- Nevus spilus
- Nevus of ota

Incision, excision, ablation, and vaporization of soft tissue in general dermatology- 532 nm Hand Piece Accessory.

Performance Data: None required. The claim of substantial equivalence is based on comparisons of specifications, characteristics, and indications for use of the claimed predicates.

CONCLUSION: Based on the information in the notification Focus Medical believes that the Focus Medical 532 Hand Piece Adapter and the Dye Pack Accessory (red or yellow) are substantially equivalent to the claimed predicates, i.e., Continuum Medlite C3 and C6 Q-Switched Nd:YAG lasers, under conditions of intended use as described in their user manuals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2004

Mr. John B. Lee, Jr.
President
Focus Medical
23 Francis J. Clarke Circle
Bethel, Connecticut 06801

Re: K032667
Trade/Device Name: Focus Medical the 532 Hand Piece Adapter and the Dye Pack Accessory (red or yellow)
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: December 12, 2003
Received: December 12, 2003

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.

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032667

Device Name: Focus Medical the 532 Hand Piece Adapter and the Dye Pack Accessory (red or yellow).

The **532 Hand Piece Adapter and the Dye Pack Accessories (Red or Yellow)**, when attached to the NaturaLase 1064 Laser, are indicated for:

Tattoo removal
- Red inks (**532 nm Hand Piece Adapter**)
- Blue and light blue inks (**Yellow Dye Pack**)
- Green inks (**Red Dye Pack**)

Treatment of Vascular Lesions - Using the 532 nm Hand Piece Adapter
- Port wine birthmark
- Telangiectasias
- Spider angiomas
- Cherry angiomas
- Spider nevi

Treatment of Pigmented Lesions - Using the 532 nm Hand Piece Adapter
- Café-au-lait birthmarks
- Solar lentigines
- Senile lentigines
- Becker's nevi
- Freckles
- Nevus spilus
- Nevus of ota

Incision, excision, ablation, and vaporization of soft tissue in dermatology - Using the 532 Hand Piece Adapter.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The Counter Use
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(510(k) Number) K032667

rev. 12/03