DEC 1 2 2012

Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: k113018

1. Date of Submission: Apr 15, 2011

2. Sponsor
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3. Submission Correspondent
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4. Proposed Device Identification

   Proposed Device Name: APOLLO V+ Medical Platform
   Proposed Device Model: MLP-01
   Product Code: GEX
   Regulation Number: 21 CFR 878.4810
   Review Panel: General& Plastic Surgery

Proposed Device Name: APOLLO IV+ Medical Platform
Proposed Device Model: MLP-02
Product Code: GEX
Regulation Number: 21 CFR 878.4810
Review Panel: General& Plastic Surgery

Proposed Device Name: Nice Station Light Based Platform
Proposed Device Model: MLP-04
Product Code: GEX
Regulation Number: 21CFR 878.4810
Review Panel: General& Plastic Surgery

Intended Use Statement:

APOLLO V+ Medical Platform / APOLLO IV+ Medical Platform / Nice Station Light Based Platform, the three models have the same intended use. They can be used in dermatology, cosmetic medicine, and other surgical applications according to the different handpieces.

The specific indications should reference to the indications of each handpiece.

1) Er:YAG laser handpiece:
- Incision, excision, ablation, vaporization of soft tissue
- The non-ablative treatment of facial wrinkles

2) Long Pulse Nd:YAG Laser Handpiece:
- Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB.

3) Q-Switch Nd:YAG Laser Handpiece:
Tattoo Removal: Dark Ink: (Black & Blue)
Nevus of Ota
Skin resurfacing procedures for the treatment of acne scars and wrinkles

4) IPL Handpiece:

The Intense Pulsed Light wavelengths are 515-1200 nm

HR (Hair Removal): 650-1200 nm

The removal of unwanted hair from skin types I-V, and to effect stable long-term, or permanent, hair reduction in skin types I-V through selective targeting of melanin in hair follicles

SR (Skin Remove): 570-1200nm

The treatment of benign pigmente (epidermal and cutaneous) lesions, such as warts.

VR (Vascular and Pigmented Lesion Removal): 515-1200nm

The treatment of benign vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider anglormas, polkiloderma of civatte; leg veins, and venous malformations.

5. Predicate Device Identification

a. ER:YAG Laser Hanpiece
K080374/ Bios Italia s.r.l/ BIOSYAG MEDICAL SYSTEM

b. Long Pulse Nd:Yag Laser Hanpiece
K072564/ Alma Laser, Ltd / Harmony XL Multiple Application Plateform

c. Q-Switch Nd:Yag Laser Hanpiece
K072564/ Alma Laser, Ltd / Harmony XL Multiple Application Plateform

d. IPL Laser Hanpiece
K024093/ Lumenis Family of Intense Pulsed-Light (IPL) and IPL/Nd:YAG Laser Systems/ Lumenis, Inc.

6. Device Description

APOLLO V+ Medical Platform / APOLLO IV+ Medical Platform / Nice Station Light Based Platform, the three models have the same modules and handpieces. The equipment configuration is the only difference among the three models.

APOLLO V+ Medical Platform is a modular multifunction device. The equipment can be used in dermatology, cosmetic medicine and other surgical according to the different handpieces. The APOLLO V+ Medical Platform has three laser handpieces of Er:YAG laser, Long Pulse Nd:YAG Laser, and Q-Switch Nd:YAG Laser, and one IPL handpiece.

APOLLO IV+ Medical Platform is a modular multifunction device. The equipment can be used in dermatology, cosmetic medicine and other surgical according to the different handpieces. The APOLLO IV+ Medical Platform has three laser handpieces of Er:YAG laser, Long Pulse Nd:YAG Laser, and Q-Switch Nd:YAG Laser, and one IPL handpiece. There is one difference between APOLLO IV+ Medical Platform and APOLLO V+ Medical Platform, it is "desktop" style for APOLLO IV+ Medical Platform, and a standard case, with wheels to allow easy movement on the floor, for APOLLO V+ Medical Platform.

Nice Station Light Based Platform is a modular multifunction device. The equipment can be used in dermatology, cosmetic medicine and other surgical according to the different handpieces. The Nice Station Light Based Platform has three laser handpieces of Er:YAG laser, Long Pulse Nd:YAG Laser, and Q-Switch Nd:YAG Laser, and one IPL handpiece. The Nice Station Light Based Platform has a standard case, with wheels to allow easy movement on the floor. The difference between Nice Station Light Based Platform and APOLLO V+ Medical Platform is the appearance.

The user can activate laser emission, IPL emission by means of a footswitch.

APOLLO V+ Medical Platform / APOLLO IV+ Medical Platform / Nice Station Light Based Platform includes:

a) Power supply
   The system provides energy for the operation of equipment.
b) Control system
   The system controls the cooling system, Laser emission and delivery system and safety features according the setting parameter which is set by user via the user interface.
c) User interface
   User sets treatment parameter via the user interface.
d) Cooling system,
   The cooling system consists of whole device cooling and IPL handpiece skin cooling.
e) Laser emission and delivery system

f) Safety features

The safety features are used to ensure the equipments is operated properly, such as key switch, emergency stop switch and interlock control unit.

g) Many handpiece types

- Er: YAG handpiece, 2940 nm wavelength
- Long Pulse Nd:YAG laser handpiece, 1064 nm wavelength
- Q-Switch Nd:YAG laser handpiece, 1064 nm wavelength
- IPL handpiece. 650-1200nm wavelengths in RH filter, 570-1200nm wavelengths in SR filter, 515-1200 nm wavelengths in VR filter.

  All of the housing of handpieces are made of ABS (Acrylonitrile Butadiene Stryene), These handpieces can be removed by the user and interchanged.

The principle of generation and treatment of energy sources

There are three kinds of energy sources, laser energy, IPL energy

- The principle of generation and treatment of laser energy

  In laser handpiece, there is one optical cavity containing the laser crystal (such as Er:YAG crystal, Nd:YAG crystal). The laser beam is activated by means of the use of Xenon lamps. This beam is directed to the treatment zone by means of a laser viewfinder. When the laser beam contacts human tissue, the energy in the beam is absorbed, resulting in a very rapidly, highly localized temperature increase to the target tissue. The instantaneous temperature increase (thermal effect) causes the cells change of target tissue to achieve laser treatment effect.
- The principle of generation and treatment of IPL energy

  In IPL module, the IPL (Intense Pulsed Light) which is activated by means of the use of Xenon lamp is directed to the treatment zone via the sapphire in selectable wavelengths. The IPL works on the principle of selective photothermolysis. That is, causing thermal damage to target tissue by using light of appropriate wavelength. The IPL is different from lasers in that it has many wavelengths in each pulse of light instead of just one wavelength. There are three filtered light guide for the selection of the wavelengths range.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60825-1: 2007, Safety of laser products - Part 1: Equipment classification, requirements.
- IEC 60601-2-22: 1995, Medical Electrical Equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.
- IEC 60601-1:1988+A1:1991+A2:1995, Medical Electrical Equipment - Part1: General requirements for safety.
- IEC60601-1-2:2001+A1:2004, Medical Electrical Equipment - Part 1: General requirements for

safety-2, Collateral Standard: Electromagnetic compatibility - Requirements and tests.

- ISO 10993-5:2009 Biocompatibility Evaluation of Medical Device, Part 5- Tests for Vitro cytotoxicity.
- ISO 10993-10:2002 Biocompatibility Evaluation of Medical Device, Part 10- Test for irritation and delay-type hypersensitivity.

8. Substantially Equivalent Conclusion

About Laser handpiece and IPL handpiece, the subject device and the predicate device have the same output energy, pulse width, repetition rate and spot size.

The subject device does not have a aiming beam compared to the predicate, but the proposed device has a focusing device (viewfinder) fitted on the handpiece head instead of aiming beam, the focusing device has the same intended use as the aiming beam, and the Biocompatibility test of the viewfinder demonstrates that the focusing device (viewfinder) does not raise the problems of safety and effectiveness.

Although the cooling method for treated skin area between the subject device with IPL handpiece and the predicate devices is different, the subject device with IPL handpiece complies with IEC 60601-1. The temperature of IPL handpiece meets the requirements which are specified in IEC 60601-1. The semiconductor absorbs the heat of the surrounding material to achieve the equivalent cooling effect.

We can't identify the power calibration (method and frequency) and disinfection method for the predicated devices, but we can provide test report to prove that the power calibration (method and frequency) and disinfection method for the subject device are safe and effective.

The proposed devices have the same energy source, similar main technological characteristics and intended use as the predicate device, based on the comparison and analysis, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Underwriters Laboratories, Incorporated
% Mr. Marc Mouser
Engineering Leader, FDA Office Coordinator
2600 Northwest Lake Road
Camas, Washington 98607-9526

December 12, 2012

Re: K113018
Trade/Device Name: APOLLO V+ Medical Platform/APOLLO IV+ Medical Platform/Nice Station Light Based Platform
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: November 26, 2012
Received: November 29, 2012

Dear Mr. Mouser:

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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Apollo V+ Medical platform / Apollo IV+ Medical Platform / Nice Station Light Based Platform, the three models have the same intended use. They can be used in dermatology, cosmetic surgery, and other surgical applications according to the different hand pieces. The specific indications should reference to the indications of each hand piece.

1. Er: YAG Laser handpiece:

Incision, excision, ablation, vaporization of soft tissue

The non-ablative treatment of facial wrinkles

2. Long pulse Nd:YAG Laser handpiece:

Removal of unwanted hair, for stable long term or permanent hair reduction, and for treatment of PFB.

3. Q-Switched Nd: YAG Laser Hand piece:

1064nm wavelength

Tattoo removal: Dark ink: (Black & Blue)

Nevus of Ota

Skin resurfacing procedures for the treatment of acne scars and wrinkles

5. IPL Handpiece:

The Intense Pulse Light wavelength are 515 – 1200nm

HR (Hair removal): 650-1200nm

The removal of unwanted hair from skin types I – V, and to effect stable long-term, or permanent hair reduction in skin types I – V through selective targeting of melanin in hair follicles.

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(Division Sign-Off)

Division of Surgical Devices

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SR (skin remove): 570-1200nm

The treatment of benign pigmente (epidermal and coutaneous) lesions, such as warts.

VR (Vascular and Pigmented Lesions Removal): 515-1200nm

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