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

November 2, 2016

Bison Medical Co., Ltd
% Young Chi
President
Bio-med Usa Inc
27 New England Dr
Ramsey, New Jersey 07446

Re: K161670
Trade/Device Name: Lucid Q-ptp / Hwa 55
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: September 27, 2016
Received: October 4, 2016

Dear Young Chi:

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" (21 CFR 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,

Jennifer R. Stevenson -A

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)*

K161670

Device Name
LUCID Q-PTP/ HWA 55

Indications for Use *(Describe)*

The LUCID Q-PTP Nd : YAG Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye hand pieces):
Tattoo removal light ink (red, tan, purple, orange, sky blue, green),
Removal of Epidermal Pigmented Lesions, Minor Vascular Lesions, Talangiectasias
Treatment of Lentigines, Cafe-Au-Lait, Sebrorrheic Keratoses,
Post Inflammatory Hyper-Pigmentation,
Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength:
Tattoo removal: dark ink (black, blue, brown)
Removal of Nevus of Ota
Removal or lightening of unwanted hair with or without adjuvant preparation
Treatment of Common Nevi, Melasma,
Skin resurfacing procedures for the treatment of acne scars, wrinkle

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 CFR 807.92(c)

1. Manufacturer.

Prepared Sept 26, 2016

BISON Medical Co., Ltd. Reg Nr: 3011555967
Ace High-end tower 6, #1801/1802
234 Beotkkot-ro, Gasan dong
GeumCheon -gu, Seoul 153-798, Rep of Korea
t: 82 2 865 7121, f: 82 2 865 7131

2. Submitter and Contact person

Bio-Med USA Inc.
Young Chi, President.
27 New England Drive, Ramsey, NJ 07446. U.S.A.
t: 1-973 278 5222 f: 1 201 934 6030
e mail: biomedusa@msn.com

3. Name of Device

Trade name	:	LUCID Q-PTP
Classification name :	:	Powered, Laser surgical instrument
Common name	:	Nd:YAG Q-switched Surgical Laser
Regulation	:	878.4810 Class II
Classification Panel	:	General and Plastic Surgery.
Product Code	:	GEX
Submission type	:	Traditional

4. Legally marketed Predicate Device

K113588	Spectra	Nd:YAG	Lutronic Corp

LUCID Q-PTP Q-Switched Nd:YAG laser system produce same two wave length (1064nm, 532nm), and same characteristics such as Design, Construction, Energy rate, Pulse Duration, applied optional Dye hand piece, Cooling system and intended use as already cleared predicate device K113588 by Lutronics.

5. Device Description

The LUCID Q-PTP Q-Switched Nd:YAG laser system produces a two pulsed beam, 1064 nm Infrared and 532nm long pulse laser, and optional 2 dye Handpieces are available that convert the 532nm wave length to 585nm and 650nm, using different Handpiece able to control various treatment fluence.
this device is non-contacted mode and consists of main function,

laser tube : placed in the mixed crystals of copper pipe to the heater and produces a laser beam,
Resonator : amplifies the beam, through the Xe-gas contained lamp
lamp : Xe-gas contains high pressure lamp to increase specific laser beam

This converted light energy creates the ND:YAG crystal and exhaust from the crystal is amplified into a specific wave length. Laser energy produced is delivered to the Tissue by means of an articulated arm and a specially designed multi spot Hand Piece.

The Physician can optimize the effect for different applications by controlling the energy of the laser pulse and the spot size of the treatment beam, and is able to activate laser emission using Foot Switch. Laser parameters and other system features are controlled from a display panel located on the front of the power supply unit.

This system also consist of
Optic main Bench assembly, Articulated Arm Hand pieces,
LCD control panel, Cooling system, Foot Pedal Switch

6. Performance test

Clinical and Non-Clinical performance test data was not provided in this submission.
But, manufactured in accordance with both mandatory and voluntary standard

IEC60601-1 part 1 : General requirement for basic safety and essential performance.
IEC60601-1-2: 2007 E M C test
IEC60601-2-22 Part 2, Particular requirements for safety of diagnostic and Therapeutic laser
IEC60825-1 :2nd ED, Equipment classification and requirement.

Lucid Q-PTP, demonstrates no significant different compare to the predicate device

7. Indication for use

The LUCID Q-PTP Nd : YAG Laser System is indicated for the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

532nm Wavelength
(nominal delivered energy of 585 nm and 650 nm with optional dye handpieces)
Tattoo removal light ink (red, tan, purple, orange, sky blue, green),
Removal of Epidermal Pigmented Lesions, Minor Vascular Lesions, Talangiectasias
Treatment of Lentigines, Cafe-Au-Lait, Sebrorrheic Keratoses,
Post Inflammatory Hyper-Pigmentation,
Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength:
Tattoo removal: dark ink (black, blue, green)
Removal of Nevus of Ota
Removal or lightening of unwanted hair with or without adjuvant preparation
Treatment of Common Nevi, Melasma,
Skin resurfacing procedures for the treatment of acne scars, wrinkle

8. Biocompatibility.

This device are non-contacted mode.
Hand piece tips is made by same material as predicate device.

9.Conclusion.

LUCID Q-PTP, Nd: YAG laser system, in this submission, is substantially equivalent to several already cleared predicate device in respect to the Intended use, Main function, Technology, Principal operation and performance.
And every Safety test report show it as safe and effective as predicate device and it does not raise any additional issues for safety and effectiveness.