DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 14, 2016

Ama Network Inc
% Young Chi
President
Bio-med Usa Inc.
27 New England Drive
Ramsey, New Jersey 07446

Re: K161981
Trade/Device Name: Olive Plus
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: June 20, 2016
Received: July 19, 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)*
K161981

Device Name
OLIVE Plus

Indications for Use *(Describe)*

Olive Plus Diode Laser device is intended for use in dermatologic and general surgical procedures for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI) including tanned skin Skin

Permanent hair reduction is defined as the long *term,* stable reduction in the number of hairs re-growing when measured at *6,* 9,and 12 months after the completion of a treatment regime.

☒ 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.

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510 (K) Summary

As required by CFR 807.92(c)

1. Sponsor, Submitter

Prepared Oct 4, 2016

AMA Network, Inc. Reg Nr: 3011287959
3600 Wilshire blvd #1016
Los Angeles, CA90010
t: 1 909 274 7700, 1 909 764 4404

2. Contact person

Bio-Med USA Inc.
Young Chi, President.
111 Ellison St, Paterson, NJ 07505. U.S.A.
t: 1-973 278 5222 f: 1 201 934 6030
e mail: biomedusa@msn.com

3. Name of Device

Trade name	:	Olive Plus
Classification name :	:	Powered, Laser surgical instrument
Common name	:	Diode Laser
Regulation	:	878.4810 Class II
Classification Panel	:	General and Plastic Surgery.
Product Code	:	GEX type : Traditional

4. Legally marketed Predicate Device

K123483 Diode Laser DLH-06 Beijing Syntech Laser

Olive Plus Diode Laser system has same characteristics such as Design, Construction, Energy rate, Pulse Duration, Cooling system and Intended Use as already cleared predicate device K123483.

5. Device Description

The Olive Plus Diode Laser system is a surgical device intended for use to remove or/and reduce un-wanted hair in Dermatologic and General Surgical procedure,
emitting 810nm diode laser to the treatment area using Hand Pieces and foot switch.
The laser beam penetrates through epidermis into dermis and absorbed by melanin in hair and hair follicle, producing laser photo thermal effect; conducting the energy from hair section to hair root, rising temperature of melanin and decomposing it, thus reaching effect of hair removal.
During the treatment, the cooling system will operated to reduce the temperature of treatment area.
Laser specification and other system features are controlled by LCD screen

This device consists of

Power supply system, Central Control System, Cooling System,
Laser Delivery system and safety features.

Hand piece tips are made by ABS plastic which are widely used in medical field.

6. Performance testing and Bench Testing

Clinical performance test data was not provided in this submission.
however, Software testing was conducted and Electrical safety testing was conducted.
This device was manufactured in accordance with both mandatory and voluntary standard.

IEC 60601-1-1:A1;2013 Medical Electrical Equipment- Part **1:** General requirements for safety.
IEC.60601-2-22: 2013 Medical Electrical Equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment.
IEC 60825-1: 2007, Safety of laser products - Part **1:** Equipment classification and requirements.
IEC 60601-1-2:2007 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance: Collateral standard: EMC test report.
IEC 62366-1:2015 Usability engineering plan
ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
ISO 10993-10:2002/Amd. 1: 2006, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity
ISO14971-2012 Software Risk Management plan
ISO13485 Software design development and maintenance activity

7. Indication for use

Olive Plus Diode Laser device is intended for use in dermatologic and general surgical procedures for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI) including tanned skin

Permanent hair reduction is defined as the long-term, stable reduction in the number of hair re-growing when measured at 6,9 and 12 months after completion of a treatment regime.

8.Comparison to Predicate Device.

	Predicate Device Diode Laser K123483 Beijing Syntech Laser	Proposed Device Olive Plus AMA Network Inc
Laser Type	Diode Laser	Diode Laser
Wavelength	808nm	810nm
Fluence	120J/cm2 (standard)	120J/cm2
Beam divergence	10(S) / 40(L)	10(S) / 40(L)
Spot size (mm)	12 x 10mm	12 x 10mm
Pulse width (ms)	5-200ms (standard)	5-200ms (standard)
Repetition rate (Hz)	1-15Hz	1-15Hz
Cooling system	Water cooling	Water cooling
Dimensions (dxwxh)	460x365x350mm	300x400x840mm
Weight	26kg	38kg

Intended use

Predicate Device : The Diode Laser is intended for use in dermatologic and general surgical procedures. The Standard Mode is intended for hair removal, permanent hair reduction. The FHR Mode is intended for hair removal, permanent hair reduction. The diode laser system is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin

Proposed Device : Olive plus Diode Laser is intended for use in dermatologic and general surgical procedures for hair removal, permanent hair reduction on all skin type (Fitzpatrick skin type I-VI) including tanned skin.
Permanent hair reduction is defined as the long term, stable reduction in the number of hairs re-growing when measured at 6,9, and 12 months after the completion of treatment regime.

9.**Conclusion**.

Olive Plus Diode 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**.**