DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 24, 2015

YOLO Medical Incorporated
% Mr. Paul Kramsky
Rockin' Regulatory Incorporated
21831 Tumbleweed Circle
Lake Forest, California 92630

Re: K143741
Trade/Device Name: Lipofina Laser System
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
Regulatory Class: Class II
Product Code: OLI
Dated: April 3, 2015
Received: April 6, 2015

Dear Mr. Kramsky:

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,

Jennifer R. Stevenson -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)*
K143741

Device Name
Lipofina Laser System

Indications for Use *(Describe)*

The Lipofina Laser System is indicated for non-invasive aesthetic treatment for the temporary reduction in circumference of the waist.

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.

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

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5.0 – 510(k) Summary for the Lipofina Laser System

5.1 Submission Sponsor:

YOLO Medical Inc.
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Surrey, British Columbia
V4A 9E3 CANADA
Telephone: 604-542-2200
Fax: 604-542-2205
FDA Establishment Registration #: TBD

5.2 Submission Correspondent:

Rockin' Regulatory, Inc.
21831 Tumbleweed Circle
Lake Forest, CA 92630
Telephone: 949-636-1464
Contact: Paul Kramsky, President
Email: pkramsky@cox.net

5.3 Date Prepared:

December 29, 2014

5.4 Device Name:

Trade/Proprietary Name:	Lipofina Laser System
Common Name:	Low Level laser System (revised)
Classification Name:	Low Level Laser System for Aesthetic Use
Product Code:	OLI
Regulation Number:	878.5400
Device Class	II Special Controls
Review Panel:	General and Plastic Surgery

5.5 Substantial Equivalence:

The Lipofina Laser System is substantially equivalent in terms of both intended use and technological characteristics to the i-Lipo™ System, which was cleared for marketing under K111501 on March 23, 2012) for non-invasive aesthetic treatment for the temporary reduction in circumference of the waist. The results of clinical testing, summarized in section 18.0 of this 510(k), confirm that the technological differences between the Lipofina and i-Lipo laser systems do not raise new issues of safety and effectiveness.

5.6 Device Description:

The Lipofina Laser System (Figure 1) consists of a main console and 8 treatment paddles. The console houses the main electronics, controls and embedded software. The liquid crystal display (LCD) identifies all key treatment parameters. The main console is also equipped with a micro controller that provides automatic calculation of energy output for a specific set of treatment parameters. The treatment paddles are constructed so that each paddle contains 12 laser emission diode sources at a power output of 35mW per laser diode. These treatment paddles are non-thermal and non-invasive, at a wavelength of 658 (central).

5.7 Indications for Use:

The Lipofina Laser System is indicated for non-invasive aesthetic treatment for the temporary reduction in circumference of the waist.

5.8 Performance Data:

Performance testing demonstrated the safety of the Lipofina Laser System in performing the waist reduction treatments. In addition, the Lipofina Laser System was tested and demonstrated to be in compliance with the IEC 60825 standard for Medical Electrical Equipment – Particular requirements for safety - Specification for diagnostic and therapeutic laser equipment, IEC 60601-2-22, Medical Electrical Equipment (3rd Edition, 2007-05), Particular Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment, IEC 60601-1, 3rd Edition, Medical electrical equipment Part 1: General requirements for basic safety and essential performance, and IEC 60601-1-2 -- Electromagnetic Compatibility (EMC), (2nd Edition, 2001) – Part 1: General Requirements for Safety; Electromagnetic compatibility.

5.9 Clinical Testing:

At the request of CDRH, a randomized, double blind clinical study was conducted in which 20 subjects were treated with the Lipofina Laser System and 21 subjects received the control (sham) device. The YOLO TOUCH LLLT successfully met the primary efficacy endpoint of this study, which was the achievement of at least 1 inch loss from baseline in averaged waistline measurement at the final visit, with 95% of subjects receiving treatment with the YOLO TOUCH LLLT device losing at least 1 inch in their waistline compared with 0 subjects in the arm receiving treatment with the sham device. In addition, no device-related AEs or skin color changes were reported for any subject during the course of this study. Taken together, these data demonstrate that the YOLO TOUCH LLLT device safely and successfully reduces waistline circumference after a course of nine 20-minute treatments in a 3-week period.