

K130341

Laser Lipo Ltd  
Heath House, Crockham Hill  
Edenbridge  
United Kingdom, TN8 6ST  
Telephone: +44 844 980 1820  
e-mail: ian@strawberry-laser.com



**510[k] Summary**  
*as required by section 807.92(c)*

**Owner's Name**

Laser Lipo Ltd

Address: Heath House  
Crockham Hill  
Edenbridge  
Kent TN8 6ST  
United Kingdom

Tel: 011 44 844 980 1820

Mobile: 011 44 777 445 9611

Fax: 011 44 1732 866 231

SEP 06 2013

**Contact Person:**

Ian Cobley at Laser Lipo Ltd

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Date this summary was prepared: January 31, 2013

**Classification name:** Low Level laser system for aesthetic use,  
21 CFR 878.5400  
79 OLI

**Common/Usual Name:** Low Level laser system for aesthetic use

**Proprietary Name:** Laser Lipo Ltd will manufacture two devices:

- The Strawberry low level laser system model ILO, and,
- The Strawberry & Cream low level laser system model SC

**Establishment Registration Number:**

The Strawberry low level laser system and Strawberry & Cream low level laser system will be manufactured by:

Laser Lipo Ltd  
Heath House  
Crockham Hill  
Edenbridge  
Kent TN8 6ST  
United Kingdom

Telephone: 011 44 844 980 1820

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Establishment Registration Number: To be applied for following clearance of this submission.

**Substantial Equivalence:** The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system is substantially equivalent in design, use and materials to the: Chromogenex Technologies Ltd I-Lipo System - K111501

- They are made of the similar materials
- They have similar indications for use that are achieved through the same technology
- They are assembled from similar components
- They have similar user input and output interfaces and
- Have similar features.

In particular both the Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system and the Chromogenex Technologies Ltd i-Lipo System:

- use laser diodes
  - of approximately 660 nm wavelength, and
  - less than 50 mW output
- incorporated into
  - multiple multi-diodes "paddles" attached to the subject with special straps
    - Strawberry 4 to 10 paddles with 6 diodes each
    - i-Lipo 4 paddles with 9 diodes each
  - and both have two probes with one diode each
- have a similar control unit
  - LCD subject display
  - membrane key pad inputs

- incorporated into display as a touch screen for strawberry and cream
  - microprocessor controlled through software
  - multi-range power supply (EU and US voltages and frequencies)
- have a similar range of connecting cables
- have the same laser protection goggles
  - different name printed on outside of frame

**Description of Product:**

The Laser Lipo Ltd Strawberry low level laser system and Strawberry & Cream low level laser system consists of a control unit, various connection leads up to 10 paddles, 2 probes, various "Velcro" attachment straps and other accessories. (A full list of system contents is included at the end of this section.)

A paddle is a device containing six cold red laser emitting diodes which is designed to be placed on the skin. The system can operate using 4, 6, 8 or 10 paddles that are connected to the control unit.

A probe is a device containing one cold red laser emitting diode which is designed to be placed on the skin to treat specific smaller areas of fat, where a usual flat paddle won't ergonomically fit.

The control unit is an electrically powered unit (100-240v, 50-60Hz auto-ranging), enabled by a main switch and key switch. Once enabled it is controlled using a button (Strawberry) or touchscreen (Strawberry and Cream) interface. The output of the diode (six per paddle) is limited to 40mW +/- 15% by a power limiting PCB from the central processing unit.

When the laser paddles are placed on the skin, the cold red laser beams penetrate the skin just deep enough to reach the layers of fat. When the light hits the fat cells, a rapid chain of events takes place. Firstly, pores form on the cells causing them to spill out. The water, Glycerol and fatty acids move into the interstitial space beneath the fatty layer in the skin. Then further water, fatty acids and Glycerol spill out. The adipocyte cells are therefore reduced in size.

**Intended use:**

The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

**Performance Data:**

Laser wavelength and output has been demonstrated to be capable and substantially equivalent to the predicate device (Chromogenex i-Lipo, K 111051).

Test	Mean	Quantity	Sample Standard Deviation	Capability, Cp
Laser diode power output: Paddle Laser diode output is set to 40mw +/-15%.	39.35	1140	0.81	2.47
Probe Laser diode output is set to 40mw +/-15%.	39.02	40	0.72	3.49
EU portable appliance testing	100% pass	20		
Visual Inspection: <ul style="list-style-type: none"> <li>• external components, cables, outer casings and the</li> <li>• General condition of all associated parts.</li> </ul>	100% pass	20		100% inspection
Assembly tests	100% pass	20		100% inspection
Functionality tests	100% pass	20		100% inspection

**Double blind clinical study:** Laser Lipo Ltd, at the request of the CDRH, had a full double blind clinical study carried out using a total of 35 subjects. Of these, 22 subjects received active laser treatments, and the remaining 13 subjects received placebo treatments. (See section 20.)

**Conclusions:** At the conclusion of the study, it was clear that 95% of the actively treated subjects achieved, or met, the success criteria. The criteria was set as achieving a temporary reduction around the subjects abdomen (at the height of the iliac crest) of 1.6in (4cm). The average recorded loss was 3.68in (9.35cm) with the greatest loss at 5.6in (14.22cm). Out of the 22 treated subject one failed to meet the criteria with a reduction of only 1.2in (3cm). Thus proving the efficacy of the Strawberry and Strawberry & Cream inch loss device.

Not one of the placebo subjects achieved more than 1.3in (3.3cm).

No adverse effects were experienced by any of the trial subjects.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WC66-G609  
Silver Spring, MD 20993-0002

Laser Lipo Ltd  
Mr. Ian Cobley  
Heath House, Crockham Hill  
Edenbridge, Kent  
TN8 6ST  
United Kingdom

September 6, 2013

Re: K130341

Trade/Device Name: Laser Lipo Ltd Strawberry Low Level Laser system and Strawberry and Cream Low level Laser system  
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: OLI  
Dated: July 26, 2013  
Received: July 29, 2013

Dear Mr. Cobley:

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

Page 2 – Mr. Ian Cobley

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 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>. 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 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,

**Mark N. Melkerson -S**

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

Enclosure

**Indications for Use**

510(k) Number (if known): K130341

Device Name: Laser Lipo Ltd Strawberry Low Level Laser system and Strawberry and Cream Low level Laser system

Indications for Use: The Low level Laser model Strawberry and Strawberry and Cream can be used for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.

Prescription Use  X

AND/OR

Over-The-Counter Use \_\_\_\_\_

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden

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(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number  K130341