MAR 2 3 2012 K111501

510(k) Summary

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

A. Submitter:

Chromogenex Technologies Limited
Units 1-2 Heol Rhosyn
Parc Dafen
Llanelli
Carmarthenshire SA14 8QG
UK

Phone: +44 (0) 1554 755444
Fax: +44 (0) 1554 755333

Contact: Mr Peter R Bevan (Quality Manager)

Date Prepared: May 2011

B. Device Names:

Classification name	Low Level Laser System for Aesthetic Use
Common/usual name	Low Level Laser System
Proprietary name	i-lipo™ System

C. Predicate Devices:

Chromogenex Technologies Limited - ilipo Ultra System – K101366
Erchonia Medical Inc – Erchonia ML Scanner – K082609

D. Device Description:

The i-lipo™ System consists of a main unit, and applied parts consisting of various laser diode cluster probes and pads. The Main Unit contains the mains input, fuses, power supply, relay, control circuits, LCD display, membrane function buttons, emergency stop, and key switch. The cluster probes and pads, which are placed against the patients skin, contain the Laser diodes. Laser energy promotes disruption of adipocyte cells within the fat layer for release of fat and lipids from these cells for non-invasive aesthetic use.

E. Intended Use:

The Chromogenex Technologies Limited i-lipo™ Low Level Laser System is indicated for Non-invasive aesthetic treatment for the temporary reduction in circumference of the waist.

F. Comparison with the Predicate Devices:
The i-lipo™ is substantially equivalent to the predicates with respect to intended use and technological characteristics.

G. Clinical Testing
Randomised, blinded, placebo controlled circumferential reduction studies of the selected treatment area have been performed, which demonstrates the efficacy of the device, following 8 sessions of treatment each of 20 minutes duration, delivered 2 to 3 times per week over a 3 week period. After each treatment session, a 30-40 minute cardiovascular exercise was completed, based upon the participants existing exercise regimen. Exercise sessions ensure that released fatty acids and glycerol are utilised rather than restored back in the body.

H. Non Clinical Testing
Safety testing has been performed to EN 60950 for General Safety and, EN60601-2-22 and EN60825 standards for Medical Electrical Equipment - Particular requirements for safety - Specification for diagnostic and therapeutic laser equipment. Electromagnetic compatibility has been tested to EN60601-2 - Medical Electrical Equipment - Part 1: General Requirements for Safety 2.

I. Conclusion
Based on the technological characteristics and clinical testing, the i-lipo™ is substantially equivalent to the above named predicate devices, for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Chromogenex Technologies Limited
% Mr. Peter R. Bevan
Quality and Regulatory Manager
Units1 and 2 Heol Rhosyn
Parc Dafen
Llanelli
Carmarthenshire SA14 8QG

MAR 2 3 2012

Re: K111501
Trade/Device Name: i-lipo™ System
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
Regulatory Class: II
Product Code: OLI
Dated: March 5, 2012
Received: March 7, 2012

Dear Mr. Bevan:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K111501

Device Name: i-lipo™ System

Indications for use:

The i-lipo™ Low Level Laser System is indicated for Non-invasive aesthetic treatment for the temporary reduction in circumference of the waist.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111501