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

Lumanosity, Inc.
% Mr. Jeff Provissiero, CFO
11271 Ventura Boulevard, Suite 212
Studio City, California 91604

OCT 4 2010

Re: K100213
Trade/Device Name: Lumanosity, Inc. Celebrity 500, Celebrity 7000
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: September 29, 2010
Received: September 29, 2010

Dear Mr. Provissiero:

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,

For Mark N. Melkerson DeP Dir

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

Enclosure

K100213

Indications for Use

510(k) Number (if known): K 100213 / S1

Device Name: Lumanosity inc. Celebrity 500, Celebrity 7000

Indications for Use:

Temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for aKm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100213

EXECUTIVE SUMMARY

501k Submission , Submission date: 1-10-2010

Submitter:

Lumanosity inc,
11271 Ventura Blvd, # 212
Studio City, CA 91604

Common Device name: Infra-red Therapy

Trade Name: The Celebrity 204

Class Name:	Lamp, infra-red, therapeutic heating
Closest Class:	II
Product code:	ILY
Regulation #:	890.5500

Purpose

The purpose for this 501k is to register a new product for sale in the market which is a finished component

Predicate Devices

Device 1 Name: TERRAQUANT SOLO PRO
510(k) Number: K080102

Controls

IEC 62471 Photobiological Safety of Lamps and Lamps Systems Part II Guidance on Mfg Requirements relating to non- laser optical radiation safety, published 2006.

Comparison Summary

A. Intended Use

The Lumanosity Celebrity is intended to deliver photomodulation therapy for the purpose of of temporarily improving pain in muscles and joints which is similar to the Terraquant Pro.

B. Technological Characteristics

Lumanosity Celebrity and Terraquant Pro both use Infrared and Red photonic energy for the purpose of temporarily improving pain in muscles and joints.

C. Differences

In addition to the LED's, the TQ Pro contains a magnet, which the Lumanosity does not.

D. Argument for Substantial Equivalence to Predicate Devices

The intended use and the technological characteristics of the Lumanosity Celebrity are the same as the predicate device and therefore we believe it is Substantially Equivalent to it.