K070252

SEP - 4 2008

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510(k) Summary

Nutritone™ Facial Beauty System

Common/Classification Name:

Stimulator, Transcutaneous Electrical, for Cosmetic Use

21 CFR 882.5890

Sponsor:

Isomers Laboratories, Inc.
Attn: Dariush Majlessi, President
105 Tycos Drive,
Toronto, ON, M6B 1W3
Canada

Contact:

RegTech Solutions, LLC
Attn: Robert Mazzaferro, Manager
11 Dellcastle Court
Montgomery Village, MD 20886

Prepared: September 9, 2007

LEGALLY MARKETED PREDICATE DEVICE

For its indication for use, the Nutritone™ Facial Beauty System is substantially equivalent to the Face Master Facial Toning System cleared by FDA under K040871.

DEVICE DESCRIPTION

The Nutritone™ Facial Beauty System is a battery-powered hand-held non-prescription device. Its output is a series of electrical pulses that are delivered to the user's face via electrodes that are built into the body of the device. A table comparing the intended use and mechanical and electrical properties of this device is presented below.

SUBSTANTIAL EQUIVALENCE SUMMARY

A comparison of the Nutritone™ Facial Beauty System and the Face Master Facial Toning System is presented in the table below.

Table 1 Comparison of New Device & Predicate Device

Specification	New Device - Isomers Nutritone™ Facial Beauty System	Predicate - Face Master K040871
Intended Use	The device is intended to stimulate the face and it is indicated for cosmetic use.	The device is intended to stimulate the face and it is indicated for cosmetic use.
Size: Body	45mm wide x 30mm thick x 131.5mm long	Not known
Weight	Mass is about 95 grams	Not known
User interface	Treatment area slide switch, thumbwheel output control and a lighted "on" indicator.	LCD display, on-off switch, and program & intensity selectors
Housing materials and construction	Housing made from ABS plastic & output contacts made from brass with a conductive silver coating.	Housing material not known. Device has external probes that plug into it.
Output Channel	Single	Single
Energy source	One 9V alkaline battery	One 9V battery
Timer range	Stimulation time controlled manually. Maximum fixed "on" time is 3- or 12-minutes depending on the selected treatment area	Stimulation time controlled manually. No apparent maximum fixed "on" time
Max $V_{0\text{-}pk}$ into 10kΩ	7.5	7.0
Waveform	Rectangular bipolar pulses	Rectangular bipolar pulses
Frequency & Pulse Width	Either 0.6Hz & 400ms or 5.3Hz & 50ms depending on treatment area	Either 0.6Hz & 400ms or 5.3Hz & 50ms depending on treatment area
Duty cycle	50%	50%
User controls	Uncalibrated thumbwheel on-off/amplitude & mode (treatment area) slide switch	On-off switch and program & amplitude selectors
Software or microprocessor	None is used	Not known
Compliance with 21 CFR 898	Not applicable. Device does not have external leads.	Complies with this standard.

Comparison of the toning gels and solutions used by the Nutritone™ & FaceMaster devices plus one other similar cleared device revealed the composition of each product is very similar.

CONCLUSION: Since the intended use is the same and the technological characteristics are so similar we believe that this pre-market submission demonstrates substantial equivalence (SE) to a legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 4 2008

Isomer Laboratories, Inc.
% Regtech Solutions, LLC
Mr. Robert Mazzaferro
11 Dellcastle Court
Montgomery Village, Maryland 20886

Re: K 070250
Trade/Device Name: Nutritone™ Beauty System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NFO
Dated: June 5, 2008
Received: June 6, 2008

Dear Mr. Mazzaferro:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Nutritone™ Facial Beauty System

Indications for Use: The Nutritone™ Facial Beauty System is intended to stimulate the face. The device is indicated for cosmetic use.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Per 21 CFR 801 Subpart D) (Per 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)

Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070250