DEC - 9 2011

510(k) SUMMARY K 102494

DAKA Industrial LTD.

Device: The Buzz Facial Toning System

1. General Information Date Prepared: November 1, 2011

Submitter: AEGIS Regulatory, Inc.
1131 Anthem View Lane
Knoxville, TN 37922
Tel.: (865) 982-5552
Fax: (865) 381-1808
Contact: Robert T. Wagner
Email: bob@fdalistingconsultants.com

On Behalf of: DAKA Industrial Limited.
Dali District, Qingxi Town
Dongguan City, Guangdong Province
Tel.: 86- 769- 8730- 9666
Fax: 86- 769- 8731- 4119
Contact: Lawrence Chan
Email: sannychi@newford.com

2. Names and Code

Device Proprietary Name: The Buzz Facial Toning System

Classification Name: TENS Device for aesthetic use.

Classification Code: NFO, Class II

Indications: Indicated for cosmetic use.

3. Predicate Devices

a. K011935 –Salton Inc- Rejuvenique
b. K040871-FaceMaster of Beverly Hills- Facemaster
c. K072260-Carol Cole Company- Nuface
d. K070217 –Neuro Resource Group-Interx 1000
e. K070250- Isomers Lab-Nutritone Facial System
f. K071573- Fatrotek SRL- Rugalift

Please see attached Predicate Chart

4. Device Description

The Buzz Facial Toning System is a TENS device that applies an electrical current to electrodes on a person's skin for aesthetic purposes.

5. Substantial Equivalence

The Buzz Facial Toning System employs the same indications for use and technological characteristics, including design materials, and power output as the predicates listed on the chart specifically K011935 Salton's Rejuvenique. Therefore substantial equivalency is requested.

6. Biocompatibility

The patient contact materials in the Beauty Buzz device are stainless steel . nodules, body of the device and the Collagen Conductive Gel.

The nodules in contact with the face are stainless steel and the body is constructed of ABS plastic and are the same materials used in predicate devices. The biocompatibility of these products are well known and considered safe when in contact with healthy skin.

A review of the Biocompatibility decision is shown on the "General Program Memorandum - #G95-1, Attachment C, Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s." Please see the following page. Following the Biocompatibility flowchart, the Beauty Buzz Collagen Conductive Gel is the same material, follows the same manufacturing process, is the same chemical composition, and has the same body contact as the legally marketed predicate device, Dezac, Conductive Gel, K022006 and therefore Biocompatibility Requirements are met.

7. Indications for Use / Intended Use

The Buzz Facial Toning System is an Over-The-Counter handheld device indicated for cosmetic use.

8. Performance Data

Taking into consideration the statement in "5. Substantial Equivalency" above, after an analysis of the safety, indications and intended uses,

performance, features, technological properties and methods of operation. The manufacturer believes that no significant differences exist between the device and the predicates listed in Section 3 (on attached chart).

OTC variance is requested.

9. Software Validation – Report follows

10. Sterilization / Use – N/A

11. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety – EN Standards testing reports are attached.

12. Performance Testing – Bench – N/A

13. Performance Testing – Animal – N/A

14. Performance Testing – Clinical – N/A

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

DAKA Industrial Limited
c/o Mr. Robert T. Wagner
Chief Executive Officer
AEGIS Regulatory, Inc.
1131 Anthem View Lane
Knoxville, TN 37922

JUN - 1 2012

Re: K102494
Trade/Device Name: Beauty Buzz Facial Toning System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NFO
Received: November 28, 2011

Dear Mr. Wagner:

This letter corrects our substantially equivalent letter of December 9, 2011.

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,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE STATEMENT

510(k) Number: K102494

Device Name: Beauty Buzz Facial Toning System

Indications for Use:

The Beauty Buzz Facial Toning System is indicated for cosmetic use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use ____
(Per 21 CFR 801.109)

Over-The-Counter Use__X___
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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