K122725

510(k) SUMMARY

Syneron Beauty Inc's Tanda Pearl

NOV 27 2012

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Syneron Beauty Inc.
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Contact Person: Omri Hayet- COO

Date Prepared: September 5, 2012

Name of Device

Tanda Pearl

Common or Usual Name

Heat source for bleaching teeth

Classification Name

EEG

Predicate Devices

Glo Science LLC's Glo Brilliant Whitening Device (510(k) exempt)

Dentovations Inc.'s South Beach Smile Light Whitening System (K042153)

CAO Group Inc.'s SonX 35 Ultrasonic Bleaching System (K041392)

Intended Use / Indications for Use

The Tanda Pearl is an over-the-counter device intended for teeth bleaching. The Tanda Pearl uses low electrical current to accelerate the action of the bleaching agent to improve the whitened appearance of teeth.

Technological Characteristics

The Tanda Pearl device consists of a double biting mouth tray made of silicone for bleaching both the upper and bottom teeth simultaneously. A bleaching agent is applied to each side of the mouth tray. The device is battery operated and turned on using a button located on the handle. Once initialized, the device delivers low amounts of electrical current (4 to 15 mA) into the bleaching medium to accelerate the teeth whitening effect caused by the bleaching medium. Once the treatment cycle has been completed, the device is automatically shut off.

Performance Data

The following performance testing was conducted to support the substantial equivalence of the Tanda Pearl:

- electrical safety (IEC 60601-1: 2005)
- electromagnetic compatibility testing (IEC 60601-1-2: 2007)
- device integrity testing (packaging/transport) (ISTA 2 Series: Partial Simulation Performance Tests- Procedure 2A)
- biocompatibility assessment (IEC 10993-1:2009)
- software verification and validation testing and (IEC 62304: 2006)
- risk analysis (ISO 14971: 2009)

All of these tests confirmed that the Tanda Pearl performs as intended.

Clinical Performance Data

In addition to the non-clinical data that supports the high degree of similarity between the Tanda Pearl and its predicates, the results of a single site IRB clinical study performed under the original technology developer, Fluorinex Active Ltd., further support a finding of substantial equivalence:

The following key results of the study further support the efficacy and safety of the Tanda Pearl device:

- The Tanda Pearl device produced significantly greater improvement in tooth whitening than the control, as measured using both the Vita Shade scores and the Vita Shade Delta-E scores. Significant results were maintained through 6 months.
- With respect to safety, no significant safety concerns were noted and all reported events associated with the Tanda Pearl device were rated as mild in severity and all were followed to resolution.

Substantial Equivalence

The Tanda Pearl is substantially equivalent to the Glo Science LLC's Glo Brilliant Whitening Device (510(k)-Exempt), Dentovations Inc.'s South Beach Smile Light Whitening System (K042153) and the CAO Group Inc.'s SonX 35 Ultrasonic Bleaching System (K041392).

The Tanda Pearl has similar intended use, similar technological characteristics, and principles of operation as its predicate devices. The technological differences between the Tanda Pearl and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that these minor differences do not adversely impact the safety of the device for its intended use. The Tanda Pearl is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Syneron Beauty, Incorporated
C/O Janice M. Hogan, Esq.
Partner
Hogan Lovells US, Limited Liability Partnership
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

NOV 27 2012

Re: K122725
Trade/Device Name: Tanda Pearl
Regulation Number: 21 CFR 872.6475
Regulation Name: Heat Source for Bleaching Teeth
Regulatory Class: I
Product Code: EEG
Dated: November 16, 2012
Received: November 20, 2012

Dear Ms. Hogan:

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,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122725

Device Name: Tanda Pearl

Indications for Use: The Tanda Pearl is an over-the-counter device intended for teeth bleaching. The Tanda Pearl uses low electrical current to accelerate the action of the bleaching agent to improve the whitened appearance of teeth.

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)

Robert S. Betz
2012.11.21 12:13:21 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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