K063704

FDA 510K Summary of Safety and Effectiveness for BriteWhite Teeth Whitening System Professional

FEB 20 2007

1. General Information

Submitter:

BEKS Incorporate
401 14th Avenue NE Unit #2
Jasper, AL 35501
888-582-3650
205-384-3940 Fax

Contact Person:

Jill Creasy
JC Consulting
694 Bluff St. #104
Carol Stream, IL 60188
630-480-0476
jcconsulting@comcast.net

Summary Preparation Date: December 3, 2006

2. Device Name

Proprietary Name: BriteWhite Teeth Whitening System (Professional)

Classification Name: Light source for bleaching teeth (21 CFR 872.6475).

3. Predicate Device

The BriteWhite Teeth Whitening System Professional is substantially equivalent in respect to the intended use, design and method of operation to numerous cleared devices, including; the South Beach Smile Light Whitening System (K042153), QuickSmile (K052040).

4. Device Description

The BriteWhite Teeth Whitening System device that utilizes Light Emitting Diodes to provide a tooth whitening system, the whitening light source is a mouth piece which is placed inside the mouth, using barrier sleeves, which emits a biologically safe and effective level of blue visible light. The general wavelength for the mouth piece is 400 nanometer spectrums to provide a selected wavelength which activates the whitening gel to bleach the teeth without the aide of heat. To ensure user safety when operating the light, the system has a built in feature to eliminate any risk for the end user and professional. The light automatically shuts off after a specified period of time. Secondly, the light source in placed inside the mouth, so there is no need for safety glasses for the patient and professional. No contact with the eyes is in this area of treatment and prevents penetrations of blue wavelength and protects the vision of the patient and professional.

5. Indications for Use:

1. The BriteWhite Teeth Whitening System is intended to emit light in the 400 nanometer spectrums to provide a light source for bleaching of teeth.

6. Technical Characteristics

The BriteWhite Teeth Whitening System and the aforementioned predicate devices are the light source for bleaching teeth as defined in 21 CFR 898.6475.

The BriteWhite Teeth Whitening System is an economical tooth whitening light which in conjunction with the whitening gel and tooth whitening preconditioning mouth wash provides a light source for bleaching the teeth. The BriteWhite Teeth Whitening System has similar intended use and technological characteristics to the predicate devices. The primary difference is the BriteWhite Teeth Whitening System uses an inside the mouth, hand piece.

7. Conclusions

The BEKS Inc. BriteWhite Teeth Whitening System has the same intended use, with similar functional and performance characteristics. The BEKS Inc. BriteWhite Teeth Whitening System performs as intended and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BEKS Incorporated
C/O Ms. Jill Creasy
JC Consulting
694 Bluff Street, #104
Carol Stream, Illinois 60188

FEB 2 0 2007

Re: K063704
Trade/Device Name: BriteWhite Teeth Whitening System
Regulation Number: 21 CFR 872.6475
Regulation Name: Heat Source for Bleaching Teeth
Regulatory Class: I
Product Code: EEG
Dated: February 05, 2007
Received: February 05, 2007

Dear Ms. Creasy:

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.

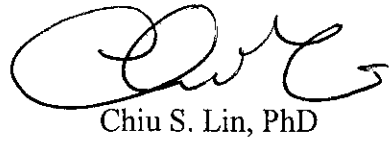
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063704

Device Name: BriteWhite Teeth Whitening System

Indications for Use:

BriteWhite Teeth Whitening System is intended to emit light in the 400 nanometer spectrum to provide a light source for the bleaching of teeth.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of [illegible] General Hospital,
Infection [illegible]

510(k) Number K063704 Page 1 of 1