OCT 1 8 2005

K052040

Cosmetic Dental Materials QuickSmile Whitening Light
Original Premarket 510(K) Notification

SECTION 9: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR.807.92.

9.1 SUBMITTER INFORMATION

a. Submitter Name:	Cosmetic Dental Materials Inc. (CDM Inc.)
b. Submitter Address:	812 Water St. NE Albany OR 97321
c. Submitter Telephone:	(541)928-4444
d. Submitter Facsimile:	(541)928-2444
e. Contact Person:	Bob Bowers Chief Operating Officer
f. Date Summary Prepared:	June 17th 2005

9.2 DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	QuickSmile
b. Classification Name:	Heat Source for Bleaching Teeth 21 CFR 872.6475

9.3 IDENTIFICATION OF PREDICATE DEVICES

The QuickSmile light is substantially equivalent to the South Beach Smile Light Whitening System by Dentovations Inc of Boston MA (510K #K042153).

9.4 DEVICE DESCRIPTION

The QuickSmile light is intended for use by a dental professional as a tooth whitening system. The whitening light heat source is a stand alone unit which emits a biologically safe and effective level of red visible light, which can penetrate the tooth and activate the photoactive substances within the tooth yielding a minimal amount of heat. The general wavelength is 600-700 nanometers. The LED light emits approximately 1°-3° C heat against the tooth surface. To ensure user safety when operating the light, the light has built in features to eliminate any risk for the end user and dental professional. First, the light automatically shuts off after a specified period of time designated by the dental professional. Secondly, the light is supplied with specially designed safety glasses for the patient and dental professional that stop the penetration of the red/orange wavelength and protect the vision of the patient and dental professional.

9.5 SUBSTANTIAL EQUIVALENCE

The QuickSmile product is a Light Emitting Diode (LED) light that emits light in the 600-700 nanometer spectrum to provide a heat source for the bleaching of teeth. The QuickSmile light is substantially equivalent to other tooth whitening lights currently in commercial distribution such as the BriteSmile and Discus Dental Zoom light. For the purpose of this 510K, the QuickSmile light will be shown to be substantially equivalent to the South Beach Smile Light Whitening System by Dentovations Inc of Boston MA (510K #K042153).

9.6 INDICATIONS FOR USE

The QuickSmile light is intended to emit light in the 600-700 nanometer spectrum to provide a heat source for bleaching teeth.

9.7 TECHNOLOGICAL CHARACTERISTICS

The Light Emitting Diodes (LED's) which are the basis of the QuickSmile whitening system are Red-Orange (613.5nm - 620.5nm) and each diode produces a typical 55 lumens per watt. Thus, the bank of 12 diodes in the adjustable head of the QuickSmile light produces about 660 lumens, a safe and effective light source for the teeth whitening process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2005

Mr. Robert Bowers
Chief Operating Officer
Cosmetic Dental Materials, Incorporated
812 Water Street N.E.
Albany, Oregon 97321

Re: K052040
Trade/Device Name: QuickSmile
Regulation Number: 21 CFR 872.6475
Regulation Name: Heat Source for Bleaching Teeth
Regulatory Class: I
Product Code: EEG
Dated: October 05, 2005
Received: October 06, 2005

Dear Mr. Bowers:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

In addition, we have determined that your device contains the following component whose regulatory status has not yet been determined: malachite green oxalate. In late 1991, the Food and Drug Administration sent letters to manufacturers and/or distributors of tooth whitening preparations (such as the bleaching gel contained in your device) advising them that the Agency considered the product drugs and "new drugs" as defined in the Federal Food, Drug, and Cosmetic Act (the Act). Under the provisions of the Act, a "new drug" may not be legally marketed in this country unless it is the subject of an approved New Drug Application (NDA). The NDA must contain adequate scientific data, including clinical trials, which establish that a product is safe and effective for its intended use.

As a result of a court case brought by one of the manufacturers, the agency agreed to further evaluate the status of tooth whitener preparations to determine whether they should be regulated as "new drugs" or cosmetics. The agency has not yet completed that further evaluation. The status of malachite green oxalate, the whitening component of your device, is unresolved at this time.

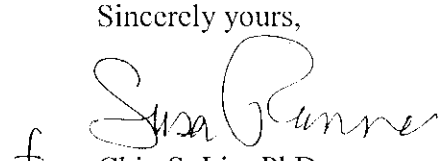
Our substantially equivalent determination does not apply to the whitening component(s) of your device.

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); 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. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on the 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 Part 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 (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for 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

Indications for Use

510(k) Number (if known): K052040

Device Name: QuickSmile
Indications for Use:

The QuickSmile light is intended to emit light in the 600-700 nanometer spectrum to provide a heat source for bleaching 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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052040