

K040797

APR - 2 2004

**510(k) Summary
for
BriteSmile Masking Cream**

1. SPONSOR

BriteSmile, Inc.
490 Wiget Lane
Walnut Creek, CA 94598

Contact Person: Steven Miller
Telephone: 925-941-6260

Date Prepared: March 26, 2004

2. DEVICE NAME

Proprietary Name: BriteSmile Masking Cream
Common/Usual Name: Gingival isolation material
Classification Name: Rubber Dam

3. PREDICATE DEVICE

BriteSmile Barrier Material, K010935

4. INTENDED USE

The BriteSmile Masking Cream is intended to be used as an accessory to the BriteSmile Barrier Material to protect soft tissue during teeth-whitening procedures.

5. DEVICE DESCRIPTION

The BriteSmile Masking Cream protects the lips and mucosal areas farther away from the teeth that will not come into contact with the teeth whitening gel but which may be exposed to heat from the BriteSmile lamp used to activate the bleaching gel during the teeth whitening procedure. The BriteSmile Masking Cream is a white cream with a pH of 6.5 to 7.0.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The BriteSmile Masking Cream is intended to be used with and has the same intended use as the BriteSmile Barrier Material. The Barrier Material protects the gingival areas adjacent to the teeth from the bleaching agent, a neutral pH, 15% hydrogen peroxide gel, and the masking cream reduces the transmission of heat generated by the BriteSmile Whitening lamp through to the soft tissue, thus maintaining patient comfort during the whitening procedure. Testing completed in conformance with established design control procedures to validate the safety and performance of the Masking Cream included biocompatibility, functionality, shelf life, and antimicrobial testing.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BriteSmile, Incorporated
C/O Ms. Sheila Hemeon-Heyer, JD, RAC
Director of Regulatory Services
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K040797

Trade/Device Name: BriteSmile Masking Cream
Regulation Number: 21 CFR 872.6300
Regulation Name: Rubber Dam and Accessories
Regulatory Class: I
Product Codes: EIE and EEG
Dated: March 26, 2004
Received: March 29, 2004

Dear Ms. Hemeon-Heyer:

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 (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,


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): K040797

Device Name: BriteSmile Masking Cream

Indications for Use:

The BriteSmile Masking Cream is intended to be used as an accessory to the BriteSmile Barrier Material to protect soft tissues during teeth-whitening procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 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

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