APR - 4 2005

K041614

REVISED 510(k) SUMMARY

Submitters Name: Joshua Friedman, D.D.S

Date of Submission: March 28, 2005

Address: AdDent, Inc.
43 Miry Brook Rd.
Danbury, CT 06810

Contact Person: Joshua Friedman

Phone: (203) 778-0200

E-mail: jfriedman@addent.com

Fax: (203) 792-2275

Device Name: Microlux/DL

Common Name: Intra Oral Examination Light

Classification Name: Light, Fiber Optic, Dental

Marketed Device of Equivalence: Visilite

Description of Device:

The Microlux/DL is used to enhance dental examination of lesions of the oral mucosa. The device consists of a battery powered light source that uses a blue-white LED, a rigid diffused fiber optic light guide. It is used in conjunction with a non-toxic dilute (1%) acetic acid rinse for the viewing of oral lesions. The fiber optic illuminator itself is non-tissue contacting, and is classified as a 510(k) Exempt FDA Device.

Intended Use: The Microlux/DL is used as an aid to improve visualization of oral lesions.

Characteristics of Microlux/DL Compared to Predicate Device:

The Microlux DL compares favorably and is substantially equivalent to another legally marketed device. The Microlux DL functions in a manner similar to and is used for the same purpose as the Speculite/OraLite manufactured by Trylon Corp. It is also sold under the name Visilite™ by Zila, Inc. The 510K number of the predicate device is K012070 and K003995.

The OraLite uses a chemical luminescent light source that produces a diffused blue-white light. The Microlux DL uses a blue-white LED and a diffused fiber optic light guide to provide a diffused blue-white light. The LED in the Microlux/DL has a color temperature of 6500°K and nominal chromaticity coordinates of X= .31 and Y =.32.

The OraLite uses a 1% acetic acid mouth rinse prior to examination. The Microlux DL uses a 1% acetic acid mouth rinse prior to examination.

Essentially, the only difference between the Microlux DL and the predicate device is that the Microlux DL uses a Blue-White LED as a light source and the Visilite uses a Blue-White chemical luminescent light source. The associated 1% acetic rinse and diagnostic procedure are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2005

Joshua Friedman, DDS
President
AdDent, Incorporated
43 Miry Brook Road
Danbury, Connecticut 06810

Re: K041614
Trade/Device Name: Microlux/DL
Regulation Number: 21 CFR 872.4630
Regulation Name: Dental Operating Light
Regulatory Class: I
Product Code: EAZ
Dated: February 3, 2005
Received: February 7, 2005

Dear Dr. Frieman:

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" (21CFR 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/industry/support/index.html.

Sincerely yours,

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

Enclosure

K041614

INDICATIONS FOR USE

510(k) Number (if known): K041614

Device Name: Microlux/DL

Indications for Use:

This device is used as an aid to improve the visualization of oral lesions. It is designed to be used by a dentist or health care provider, in combination with a traditional examination by incandescent light.

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

Susan Runner

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

510(k) Number: K041614