K062961

510(k) SUMMARY

FEB 8 2007

Submitters Name: Joshua Friedman, D.D.S

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

Phone: (203) 778-0200

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Device Name: Microlux Transilluminator

Common Name: Fiber Optic Transilluminator

Classification Name: Not officially classified

Marketed Device of Equivalence: Welch Allyn Fiber Optic Transilluminator.

Description of the Device: The Microlux Transilluminator consists of a battery powered, high output L.E.D. light source, (three 'N" size batteries are included) and a fiber-optic glass light guide with either a 3mm or 2mm tip. The fiber-optic glass light guide snaps into the light source. The fiber-optic light guide is autoclaveable. The light source can be wiped with disinfectant. Disposable custom fitted sleeves are also available the cover the entire unit to prevent cross contamination.

Intended Use: The Microlux Transilluminator is a screening device used as an aid in visualizing caries and crown fractures. It also functions as an auxiliary light source to aid in operative procedures and preventive dentistry.

Characteristics of the Microlux Transilluminator Compared to Predicate Device: The Microlux Transilluminator is based on similar construction and application as the predicate devices with the exception of the light source. The Microlux uses a L.E.D.. The Novar and the Welch Allyn both use halogen lamps. The Cameron unit uses an incandescent lamp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

FEB 8 2007

Re: K062961
Trade/Device Name: Microlux Transilluminator
Regulation Number: 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NTK
Dated: January 11, 2007
Received: January 16, 2007

Dear Dr. Friedman:

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.

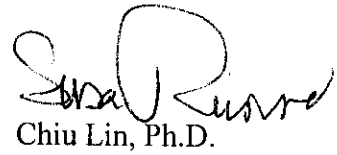
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

K062961

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Microlux Transilluminator

Indications for Use: The Microlux Transilluminator is a device used upon initial examination of the dental patient to help locate crown fractures, posterior and anterior caries.

Intended Use: The Microlux Transilluminator is a screening device used to help locate caries and crown fractures. It also functions as an auxiliary light source to aid in operative procedures and preventive dentistry.

Division Sign-Off
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K062961

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