K082668

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510(k) SUMMARY

Submitters Name: Joshua Friedman, D D S

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

Phone: (203) 778-0200

Fax: (203) 792-2275

JAN 23 2009

FDA CDRH

JAN 16 2009

Device Name: Bio-Screen

Common Name Oral Examination Light

Classification Name: Dental Operating Light

Marketed Device of Equivalence: Vizilite, Microlux/DL, Microlux/Blu, Velscope

Description of the Device: This device uses an array of short wave blue LED's in the technique of biofluorescence to demonstrate abnormal oral tissue It employs a built in optical filter to improve contrast between healthy and abnormal tissue and improve visualization

Intended Use. The Bio-Screen is intended to be used by a dentist or health care provider as an adjunct to traditional oral examination by incandescent light to enhance the visualization of oral mucosal abnormalities and aid in defining lesion borders

Characteristics of the Bio-Screen Compared to Predicate Device The Velscope made by LED Electronics, uses blue light and the principle of biofluorescence for screening and visualization of abnormal oral mucosa Velscope 510(k) No K060920 Comparison to other predicate devices is shown on page 10

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 2 3 2009

Re K082668
Trade/Device Name Bio-Screen
Regulation Number 21 CFR 872 6350
Regulation Name Ultraviolet Detector
Regulatory Class II
Product Code NXV
Dated January 15, 2009
Received January 16, 2009

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807 97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 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,

Clarence Murtin for
Ginette Y Michaud, M D
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Bio-Screen

Indication for Use:

The Bio-Screen is intended to be used by a dentist or health care provider as an adjunct to traditional oral examination by incandescent light to enhance the visualization of oral mucosal abnormalities and aid in defining lesion borders

Prescription Use __X_____ (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)

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

510(k) Number K082668