K101140

510(k) Summary
for
Dentlight Oral Exam Light Kit

JUL 15 2010

1. APPLICANT

DentLight Inc.
1411 E. Campbell Rd., Suite 500
Richardson, TX 75081

Contact Person: Richard Liu
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Date Prepared: April 9, 2010

2. DEVICE NAME

Proprietary Name: Dentlight Oral Exam Light Kit

Common/Usual Name: Oral Examination Light

Classification Name: Ultraviolet Detector (872.6350)

3. PREDICATE DEVICES

Velscope (K070523) by LED Medical Diagnostics

Sapphire O/E Oral Examination System by Den-Mat Holdings (K073483)

Identafi 3000 (K090135) by Trimira, Remicalm

4. DEVICE DESCRIPTION

Dentlight Oral Exam Light Kit is a rechargeable-battery-powered cordless unit designed for illumination and examination for dental and physician's office on any procedures which require a small homogenous and well-defined spot and natural tissue reflectance and fluorescence visualization of healthy and abnormal tissue.

Dentlight Oral Exam Light Kit consists of a cordless unit with interchangeable light head (White and Violet), custom adaptable Fluorescence Loupe Filters and Filter Caps, Charging Stand, Power Adapter, and Patient Protective Eyewear Goggle.

5. INTENDED USE

Dentlight Oral Exam Light Kit is indicated for providing illumination to aid visualization during oral procedures and an adjunct to enhance the visualization for oral examination of mucosal abnormalities and oral lesions.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANDTIAL EQUIVALENCE

Dentlight Oral Exam Light Kit is substantially equivalent to K070523, K073483, and K090135 in intended use and operation; each uses fluorescence and/or reflectance as the primary mode for enhanced visualization of tissue for determining oral tissue abnormalities.

Predicate K070523 uses 120V AC powered metal halide light to produce a single collimated blue light and views fluorescence through a connected handpiece with a filtered lens.

Predicate K073483 uses 120V AC powered Xenon plasma arc light and filters to produce a single collimated blue light and views fluorescence through a connected handpiece with a filtered lens.

Predicate K090135 uses AA-battery-powered low power LED light to produce a violet light at near site to tissue and view fluorescence through a broadband polarized filter glass. A selectable wavelength mechanism is built in with additional white and amber LED lights that compliment fluorescence image.

Dentlight Oral Exam Light Kit offers two illumination modalities and one common detection/viewing mechanism. Both illumination modalities use LED light source in multiple wavelength spectra as illumination or excitation source for tissue fluorescence/reflection. The operational principles of the proposed and predicate devices are identical with the primary mode for enhanced visualization of tissue through fluorescence. The operator chooses the appropriate wavelength light source to illuminate regions of oral cavity for inspection.

The major differences between the proposed Dentlight Oral Exam Light Kit and the predicate devices are the magnified high contrast filter used in the detection/viewing, the illumination intensity, size, weight and portability of the device. The increased light intensity of the proposed Dentlight Oral Exam Light Kit using high power LED allows the illumination and excitation with improved clarity. The improved portability with cordless hands free operation or wand operation enables better, easier and faster exam procedures. The size and weight is a benefit to constant patient operations and counter space.

7. PERFORMANCE TESTING AND COMPLIANCE

The following testing was conducted to evaluate the functionality and performance of the proposed Dentlight Oral Exam Light Kit:

- Optical Power Testing
- Optical wavelength
- Beam Quality
- Illumination and Fluorescence Image

The Dentlight Oral Exam Light Kit is designed to comply with electrical safety and electromagnetic compatibility and will comply with electrical safety requirement established by IEC 60601-1-2.

We believe the similarity of the Dentlight Oral Exam Light Kit to the legally marketed predicate devices and the performance data provided support the safety and effectiveness of the Dentlight Oral Exam Light Kit for the indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Richard Liu
President
DentLight, Incorporated
1411 East Campbell Road, Suite 500
Richardson, Texas 75081

JUL 15 2010

Re: K101140
Trade/Device Name: DentLight Oral Exam Light Kit
Regulation Number: 21 CFR 872.6350
Regulation Name: Ultraviolet Detector
Regulatory Class: II
Product Code: EAQ, NXV
Dated: April 9, 2010
Received: April 22, 2010

Dear Dr. Liu

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K101140

Device Name: Dentlight Oral Exam Light Kit

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Dentlight Oral Exam Light Kit is indicated to be used by a dentist and physician for illumination to aid visualization during oral procedures and as an adjunct to enhance the visualization for oral examination of mucosal abnormalities and oral lesions.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R S Botz DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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