K080043

172

SECTION 12 - 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS APR - 4 2008

K080043 ViziLite Eyewear

Submitter's Name: Gary Klinefelter

Date of Submission: March 24, 2008

Address: 5227 North 7th Street

Contact: Mark Bride, DDS

Phoenix, AZ 85014-2800

Phone: 602-266-6700

Fax: 602-234-2318

Consultant: Suzanne Parisian, M.D.

MD Assist, Inc.

Device Name: ViziLite Eyewear

Common Name: Oral Examination Light

Classification Name: Operating Light, Dental

Substantial Equivalence: ViziLite Blue Oral Exam Product

1. INTENDED USE:

The ViziLite Eyewear is reusable and intended to be an optional accessory worn by health care professionals during chemiluminescent oral exam.

INDICATIONS FOR USE: INDICATIONS FOR USE:

The ViziLite Eyewear is reusable polarized filtered eyewear that is worn by a health care professional to reduce the effects of ambient light during chemiluminescent oral exam when a darkened room is not available. The ViziLite Eyewear has been designed to allow transmission of 430-580nm light.

Instructions for Use "VIZILITE EYEWEAR"

The reusable ViziLite eyewear, as supported by clinical testing, allows a trained health care professional the option to use the eyewear throughout the ViziLite Plus with TBlue Oral Lesion Marking Procedure for oral chemiluminescent examination without the need for darkening a room and without altering safety and efficacy.

Following a conventional oral exam with ambient light, the trained health care professional can put on the ViziLite Eyewear for the ViziLite Plus with TBlue Oral Lesion Marking Procedure to improve oral mucosal lesion identification, evaluation and monitoring in patients at increased risk for oral cancer. The "ViziLite" is the system's chemiluminescent light source used for identification and evaluation of oral mucosal changes which can include atypia, dysplasia, leukoplakia, erythroplakia, genetic change or occult lesions.

While still wearing the ViziLite Eyewear, oral lesions identified by ViziLite can be marked using the TBlue Oral Lesion Identification and Marking System to help preserve the anatomic characteristics. The marking dye, when positive, acts as a lesion marker allowing removal of the ViziLite while preserving the anatomic characteristics of the lesion. Whether a lesion marks with dye or not should not alter the clinician's clinical behavior as dictated by the results of the ViziLite examination.

The ViziLite Eyewear can be worn throughout the ViziLite and TBlue Oral Lesion Marking procedure without interfering with the examination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2008

Mark Bride, DDS
Vice President, Medical Affairs
Zila, Incorporated
5227 North 7th Street
Phoenix, Arizona 85014-2800

Re: K080043
Trade/Device Name: VIZILITE EYEWEAR
Regulation Number: 872.6350
Regulation Name: Dental Operating Light
Regulatory Class: II
Product Code: NXV
Dated: March 25, 2008
Received: March 27, 2008

Dear Dr. Bride:

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.

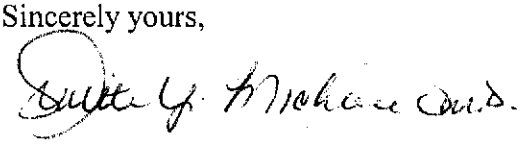
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

SECTION 1- INDICATIONS FOR USE

K080043

510(k) Number: K080043

Device Name: VIZILITE EYEWEAR

INDICATIONS FOR USE: The ViziLite Eyewear is reusable polarized filtered eyewear that is worn by a health care professional to reduce the effects of ambient light during chemiluminescent oral exam when a darkened room is not available. The ViziLite Eyewear has been designed to allow transmission of 430-580nm light.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)

Division of Anesthesiology, General Hospital,

Infection Control & Dental Devices

510(k) Number K080043