K060920

Section 5 – 510(k) Summary

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Date of Submission: March 31st 2006

Contact Person: David Morgan, PhD

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Device Name: VELscope

Common Name: Oral Examination Light

Classification Name: Operating Light, Dental

Marketed Device of Equivalence: Vizilite

Description of Device:

VELscope is a natural tissue fluorescence direct visualization system to be used as an adjunctive tool for oral mucosal examination.

The main components of VELscope are the Light Source Unit (LSU) and the viewing Handpiece. The VELscope Handpiece emits a safe, visible, blue light into the oral cavity, which excites the oral tissue and causes it to fluoresce. The oral cavity can then be examined in real time and suspicious tissue that may require further investigation can be quickly identified. When viewed through the VELscope Handpiece, healthy tissue typically shows up as a brighter green color while suspicious tissue can cause a loss of fluorescence, which thus appears dark.

Intended Use:

VELscope is to be used by qualified health-care providers to enhance the identification and visualization of oral mucosal abnormalities by exciting the tissue with blue light and allowing the direct visualization of the resulting natural tissue fluorescence. VELscope is complimentary to and is intended to be used in combination with a traditional oral mucosal examination with white light.

Characteristics of VELscope compared to Predicate Device:

The VELscope System is substantially equivalent to Vizilite, manufactured by Zila, Inc. The 510(k) number of the predicate device is K003995.

The VELscope functions similarly and is used for the same purpose as the Vizilite device.

Vizilite uses a 1% acetic acid mouth rinse prior to examination. An acetic acid rinse is not necessary for the use of the VELscope system.

Vizilite uses a chemiluminescent light source that produces a diffused blue-white light. The VELscope system uses a metal halide light to produce a blue light that is directed into the mouth via the VELscope Handpiece.

Essentially, the only difference between the VELscope system and the predicate device is that the VELscope system uses filters to block the reflected blue light to allow the visualization of the natural tissue fluorescence.

Clinical Studies:

NIH funded scientific studies provide evidence to support that VELscope is effective in enhancing the visualization of oral mucosal abnormalities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2006

Dr. David C. Morgan
Senior Vice President Product Development
Led Medical Diagnostics, Incorporated
#210-15047 Marine Drive
White Rock, British Columbia V4B 1C5

Re: K060920
Trade/Device Name: VELscope
Regulation Number: 872.6350
Regulation Name: Ultraviolet detector
Regulatory Class: II
Product Code: NXV
Dated: March 31, 2006
Received: April 4, 2006

Dear Dr. Morgan:

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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

K060920

Indications for Use

510(k) Number (if known):

Device Name: VELscope

Indications For Use:

VELscope 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.

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)

[signature]

...logy, General Hosp...
...Dental Devices

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