

K070523

192

Section 5 – 510(k) Summary

APR 5 – 2007

Submitter's Name: David Morgan, PhD

Date of Submission: February 14 2007

Address: 201-15047 Marine Dr.
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Device Name: VELscope

Common Name: Oral Examination Light

Classification Name: Ultraviolet detector

Marketed Device of Equivalence: VELscope (K060920)

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 intended to be used by qualified health-care providers to enhance the identification and visualization of oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer or premalignant dysplasia. VELscope excites the tissue with blue light and allows 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 incandescent (white) light.

VELscope is further intended to be used by a surgeon adjunctively to his/her clinical assessment to help identify diseased tissue around a clinically apparent lesion and thus

Dated: 2/14/2007

aid in determining the appropriate margin for surgical excision.

Characteristics of VELscope compared to Predicate Device:

The VELscope System is substantially equivalent to the VELscope System already cleared under 510(k) – K060920.

As compared to the predicate device, the VELscope system now has expanded indications for use based on recently published clinical data in peer-reviewed publications. These indications:

- Explicitly state the possibility of helping detect oral cancer and dysplasia
- Explicitly state the possibility of helping detect mucosal abnormalities that may not be visible or apparent to the naked eye.
- Include a new indication for use by surgeons as an aid to identifying diseased tissue around a clinically apparent lesion to help determine the appropriate margin for surgical excision.

Clinical Studies:

Peer-reviewed and published scientific studies provide evidence to support that:

- VELscope is effective in helping detect occult cancerous and dysplastic lesions
- VELscope can help an oral surgeon assess the extent of occult diseased tissue around a clinically apparent precancerous or cancerous lesion and thus aid in determining the appropriate margin for surgical excision.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

David C. Morgan, Ph.D.
Senior Vice President
LED Dental, Incorporated
201-15047 Marine Drive
White Rock, British Columbia
Canada V4B 1C5

Re: K070523
Trade/Device Name: VELscope
Regulation Number: 872.6350
Regulation Name: Ultraviolet Detector
Regulatory Class: II
Product Code: NXV
Dated: February 14, 2007
Received: February 23, 2007

Dear Dr. Marine:

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,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", with a stylized circular mark at the beginning.

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

K070 523

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 that may not be apparent or visible to the naked eye, such as oral cancer or premalignant dysplasia.

VELscope is further intended to be used by a surgeon to help identify diseased tissue around a clinically apparent lesion and thus aid in determining the appropriate margin for surgical excision.

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 IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Melby for MSR

Division of Anesthesiology, General Hospital,
FDA, Center for Device Evaluation and Research, Dental Devices

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