K102083

**510(k) Summary**

NOV 18 2010

**Submitter's Name**: David Morgan, PhD

**Date of Submission**: July 23 2010

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**Device Name: VELscope Vx**

**Common Name:** Oral Examination Light

**Classification Name:** Ultraviolet detector

**Marketed Device of Equivalence**: VELscope (K070523)

**Description of Device:**

The VELscope Vx system 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 Handpiece, incorporating light source, viewing optics and rechargeable battery, Charging Cradle and external power supply. 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, abnormal tissue typically appears as an irregular, dark area that stands out against the otherwise normal green fluorescence pattern of surrounding health tissue.

**Intended Use:**

VELscope Vx 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 and premalignant dysplasia.

VELscope Vx 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.

**Characteristics of VELscope compared to Predicate Device:**

As compared to the predicate device, the VELscope Vx system has identical Indications for Use.

The main technological differences between the VELscope Vx and the predicate VELscope system are:

- The light source has now been integrated into the Handpiece by replacing the metal halide lamp originally situated in a separate Light Source Unit with a ring of blue light emitting diodes (LED's) now situated around the distal window of the Handpiece itself.

- The VELscope Vx Handpiece can now operate in a completely cordless fashion powered by a rechargeable lithium ion battery.

The essential performance specifications of the device are equivalent to the predicate VELscope device:

- The excitation band (400-460nm) is the same as the predicate device and the optical output power in that excitation band is comparable.

- The emission (viewing) optics are identical to the predicate device.

**Non-Clinical Data**

Spectral data comparing the optical intensity distribution of the VELscope Vx excitation light with that of the predicate VELscope are provided to support substantial equivalence.

**Clinical Data**

Clinical photographs were taken of a variety of oral mucosal lesions from patients referred to oral medicine and oral dysplasia clinics. Conventional (white light) as well as fluorescence photographs using both the predicate VELscope and the VELscope Vx were acquired. No adverse events or complications were reported. A comparison of the predicate VELscope and VELscope Vx images supports the substantial equivalence of the VELscope Vx with the predicate VELscope.

**Conclusion**

The VELscope Vx system has identical indications for use as the predicate VELscope system and comparative excitation spectral data and clinical fluorescence photographs of oral mucosal lesions support the fact that, despite the technological differences, the VELscope Vx system is substantially equivalent to the VELscope system already cleared under 510(k) – K070523.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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NOV 18 2010

Re: K102083
Trade/Device Name: VELscope Vx
Regulation Number: 21 CFR 872.6350
Regulation Name: Ultraviolet Detector
Regulatory Class: II
Product Code: NXV
Dated: October 18, 2010
Received: October 29, 2010

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. 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): K102083

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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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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



510(k) Number: _____