

1082K082603

## V. 510(k) SUMMARY

Submitted by: TRIMIRA LLC  
952 Echo Lane  
Houston, TX 77024  
Phone: (713) 984-8550  
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DEC 12 2008

Contact Person: David B. Jones

Date Prepared: August 22, 2008

Proprietary Name: TRIMIRA™ OCS 3000®

Common Name: Oral Examination Light and Accessories

Classification:

Class II:	21 CFR § 872.6350
Class I: (Exempt)	21 CFR § 874.4420
Class I: (Exempt)	21 CFR § 886.5850

Classification Name: Ultraviolet Detector – NXV (EAQ)  
ENT manual surgical instrument (Mirrors) – KAI (Exempt)  
Photosensitive glasses – HQY (Exempt)

Predicate Devices:

VELscope (K070523)  
LED Medical Diagnostics  
201-15047 Marine Drive  
White Rock, BC, Canada V4B 1C5

ViziLite (K033033 & K080043)  
The Trylon Corporation  
970 West 190<sup>th</sup> Street, Suite 850  
Torrance, CA 90502-1037

Device Description:

The TRIMIRA™ OCS 3000® is a "AA" battery operated, hand-held, multispectral oral examination light used in conventional and specialized oral examination. Accessories include safety glasses and disposable mirrors.

Intended Use:

OCS 3000® 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.

OCS 3000® allows for conventional oral mucosal examination and excites the tissue with multispectral lights for direct visualization of the resulting natural tissue fluorescence and reflectance, and vasculature.

OCS 3000® is also intended to be used by a surgeon to help identify diseased tissue around a clinically apparent lesion to aid in determining the appropriate margin for surgical excision.

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OCS 3000<sup>®</sup> eyewear is reusable polarized filtered eyewear that is worn by a health care professional to enhance the visual effects of violet light during oral exam. OCS 3000<sup>®</sup> eyewear has been designed to allow transmission of 430-580 nm light.

#### Technological Characteristics:

The OCS 3000<sup>®</sup> with multispectral identifi<sup>™</sup> technology (Patent No. 7,365,844 and patents pending) uses "AA" batteries to operated high-intensity LEDs to produce white, violet and amber light. These safe, visible lights allow health professional to perform Conventional Oral Examination (COE) using white light, and specialized or enhanced visual examinations of tissue using violet and amber lights.

The OCS 3000<sup>®</sup> violet light enhances normal tissue's natural fluorescence. Visual examination under violet light shows healthy tissues in fluorescing green (when using filtered glasses) while suspicious tissue appears dark because of its loss of fluorescence. Amber light enhances the tissue's natural reflectance and makes visualization of the vasculature possible.

The direct visualization of fluorescent and reflective tissues is using the body's natural system to identify suspicious tissue quickly that may require further investigation. The loss of natural tissue fluorescence and reflectance can identify subclinical high-risk fields with cancerous and precancerous changes **Clinical Cancer Research Vol. 12, 6716-6722, November 15, 2006.**

#### Substantial Equivalence

The OCS 3000<sup>®</sup> has the same intended use and technological characteristics as the approved predicate devices (K033033, K070523, and K080043); 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 to power a metal halide light to produce a single blue light and views fluorescence through a connected handpiece with a green filtered lens. In addition, the predicate for the original VELscope (K060920) was the ViziLite (K033033).

Predicate, K033033, uses two "AA" batteries to power high-intensity LEDs to produce white light. However, predicate K033033 uses a 1% acetic acid rinses and metachromatic vital tissue dye (tolonium chloride), a post-dye decolorizer and polarized filtered eyewear (K080043) with diffuse chemiluminescent white-blue light to observe abnormalities by reflectance.

The OCS 3000<sup>®</sup>'s patented multispectral identifi<sup>™</sup> technology use LEDs produce three different light wave lengths (white, violet and amber), and polarized filtered eyewear (K080043) to enhance the fluorescence and reflectance (K070523) contrast of normal and neoplastic epithelial tissue. By filtering a selected band of autofluoresced or reflected light, the OCS 3000<sup>®</sup> allows the clinician to see enhanced contrast between normal and abnormal tissue within the overall range of white light spectra (K033033).

Unlike the predicates, the clinician may use the multispectral OCS 3000<sup>®</sup> with white light for conventional oral examinations, and violet and amber lights for visualization of the natural tissue fluorescence and reflectance. Other devices or chemicals are not required. In addition, the OCS 3000<sup>®</sup> amber light enhances visualization of the vasculature through reflectance.

The design, materials, method of operation, and labeling are substantially equivalent.

The TRIMIRA<sup>™</sup> OCS 3000<sup>®</sup> is substantially equivalent to the approved predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 12 2008

Mr. David B. Jones  
Vice President, Regulatory Affairs and Quality Assurance  
Remicalm L.L.C.  
952 Echo Lane, Suite 333  
Houston, Texas 77024

Re: K082603  
Trade/Device Name: TRIMIRA™ OCS 3000  
Regulation Number: 21 CFR 872.6350  
Regulation Name: Ultraviolet Detector  
Regulatory Class: II  
Product Code: NXV  
Dated: December 8, 2008  
Received: December 10, 2008

Dear Mr. Jones:

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.

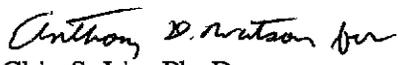
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
Chiu S. Lin, Ph. D  
Division Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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IV. Indications for Use

Applicant: TRIMIRA LLC  
952 Echo Lane, Suite 333  
Houston, TX 77024  
Phone: (713) 984-8550  
Fax: (713) 984-9232

510(k) Number (if Known): K082603

Device Name: TRIMIRA™ OCS 3000®

Indications For Use:

OCS 3000® 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. OCS 3000® allows for conventional oral mucosal examination and excites the tissue with multispectral lights for direct visualization of the resulting natural tissue fluorescence and reflectance, and vasculature. OCS 3000® is also intended to be used by a surgeon to help identify diseased tissue around a clinically apparent lesion to aid in determining the appropriate margin for surgical excision. OCS 3000® eyewear is reusable polarized filtered eyewear that is worn by a health care professional to enhance the visual effects of violet light during oral exam. OCS 3000® eyewear has been designed to allow transmission of 430-580 nm light.

Prescription Use  (Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter  (Per 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)



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

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