FORWARD SCIENCE LLC

2511 Wind Fall Ln
Sugar Land, TX 77479 USA
Ph: 855-696-7254

K123169

V. 510(k) SUMMARY

MAR 13 2013

Submitted by: Forward Science LLC
2511 Wind Fall Lane
Sugar Land, TX 77479
Ph: 855-696-7254
Fax: 855-329-6725

Contact Person: Brian Pikkula, PhD

Date Prepared: October 04, 2012

Proprietary Name: OralID™

Common Name: Oral Examination Light and Accessories

Classification:

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

Classification Name: Ultra-violet Detector – NXV (EAQ)
Photosensitive glasses – HQY (Exempt)

Predicate Devices: DentLight Oral Exan Light Kit (K101140)
DentLight Inc
1411 E. Campbell Rd, Suite 500
Richardson, TX 75081

VELscope Vx (K102083)
LED Medical Diagnostics
235 – 5589 Byrne Road
Burnaby, BC, Canada, V5J 3J1

Device Description:

OralID™ is a battery operated (CR123A), hand-held, oral illumination and examination light designed for use by dental and medical professionals to be used as an adjunctive tool for fluorescence visualization of oral mucosal tissue. OralID™ accessories include two pair of filtered eyewear for both the clinician and patient.

Intended Use:

OralID™ is intended to be used by a dentist or physician as an adjunct to an oral examination to aid in visualization of oral mucosal abnormalities, such as oral cancer and pre-cancer.

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Technological Characteristics:

OralID™ uses "CR123A" batteries to operate one high intensity LED to emit a visible blue light to aid in visualization of oral mucosal abnormalities, such as oral cancer and pre-cancer. While using the filtered glasses and OralID™ oral examination light, healthy tissue fluoresces while abnormal tissue appears dark due to lack of fluorescence.

Substantial Equivalence

OralID™ has the same intended use and technical characteristics as the predicate devices (K101140 and K102083); each uses fluorescence as the primary mode to aid in visualization of tissue for determining oral tissue abnormalities.

Predicate K101140 uses rechargeable batteries to power high-intensity LEDs that produces a violet light and views fluorescence through filtered loupes.

Predicate K102083 uses rechargeable lithium ion batteries to power high-intensity LEDs that produce blue light and views fluorescence through a hand piece with a filtered lens.

OralID™ uses "CR123A" batteries to power a high-intensity LED that produces blue light as illumination for excitation for tissue fluorescence viewed through filtered eyewear.

The only technological difference from the predicate devices is the power source. While both predicate devices use rechargeable batteries, OralID™ uses primary CR123A batteries to power the device, which decreases the electrical safety risk of the recharging process.

The operational principles of the proposed and predicate devices are identical with the primary mode to aid in visualization of tissue through fluorescence. Each of these devices is powered by batteries and uses LED technology to illuminate the oral cavity view the tissue fluorescence through a filtered lens.

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

OralID™ is substantially equivalent to the cleared predicate devices.

Performance Testing and Compliance

The following tests were conducted to evaluate the functionality and performance of the proposed OralID™ oral examination light:

- Optical Safety
- Thermal Safety
- Optical Wavelength
- Optical Power Testing
- Beam Quality

OralID™ conforms to electrical safety requirements and complies with the electromagnetic compatibility standards established by IEC 60601-1-2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2013

Dr. Brian Pikkula
President & CTO
Forward Science LLC
2511 Wind Fall Lane
SUGAR LAND TX 77479

Re: K123169
Trade/Device Name: OralID™
Regulation Number: 21 CFR 872.6350
Regulation Name: Ultraviolet Detector
Regulatory Class: II
Product Code: NXV
Dated: February 6, 2013
Received: February 11, 2013

Dear Dr. Pikkula:

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,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FORWARD SCIENCE LLC

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IV. Indications for Use

Applicant: **Forward Science LLC**
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Ph: 855-696-7254
Fax: 855-329-6725

510(k) Number (if Known): K123169

Device Name: **OralID™**

Indications For Use:

OralID™ is intended to be used by a dentist or physician as an adjunct to an oral examination to aid in visualization of oral mucosal abnormalities, such as oral cancer and pre-cancer.

Prescription Use____X____ AND/OR Over-the-Counter_____
(Per 21 CFR 801 Subpart D) (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)

Mary S. Runner -S
Susan Runner, DDS, MA 2013.03.13
13:22:37 -04'00'

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

510(k) Number: K123169