A. **Submitter Information**  
Quantum Dental Technologies Inc.  
748 Briar Hill Avenue  
Toronto, Ontario  
M6B 1L3, Canada  

**Contact Person:**  
Josh Silvertown, PhD  
Vice President  
Quantum Dental Technologies Inc.  
748 Briar Hill Avenue  
Toronto, Ontario  
M6B 1L3, Canada  

Phone: 1-866-993-9910 ext 103  
Fax: 1-866-993-9916  
josh@thecanarysystem.com  

**Date Prepared:** Tuesday, October 09, 2012

B. **Device Identification:**

<table>
<thead>
<tr>
<th>Classification Name</th>
<th>Laser fluorescence caries detection device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary Name</td>
<td>The Canary System</td>
</tr>
<tr>
<td>Device Classification</td>
<td>Class II</td>
</tr>
<tr>
<td>Panel</td>
<td>Dental</td>
</tr>
<tr>
<td>Device Product Code</td>
<td>NBL</td>
</tr>
<tr>
<td>Previous FDA Status</td>
<td>The Canary System has no prior FDA Status</td>
</tr>
<tr>
<td>Basis for Submission</td>
<td>New Device</td>
</tr>
</tbody>
</table>

C. **Identification of Predicate Device:**

<table>
<thead>
<tr>
<th>Device</th>
<th>Applicant</th>
<th>510(k) No.</th>
<th>Date Cleared</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIGNOdent</td>
<td>KAVO DIGNODENT</td>
<td>K983658</td>
<td>February 22, 2000</td>
</tr>
<tr>
<td>SOPRO Life</td>
<td>SOPRO</td>
<td>K092583</td>
<td>January 13, 2010</td>
</tr>
</tbody>
</table>

D. **Device Description:**

The Canary System™ uses a low powered 660 nm wavelength laser to examine the tooth surface. When this laser light is shone on the tooth the laser light is scattered and absorbed. An absorbed portion of the light is converted into heat and emits thermal infrared (Photothermal Radiometry, PTR) and another part of the light excites the tissue and emits optically converted light (Luminescence; LUM), which shows the difference between what appears to be healthy tooth structure and areas suspected of being carious tooth structure. Compared to a healthy tooth, areas suspected of being carious or possibly having other defects such as micro cracks absorb more light and generate higher PTR signals and lower LUM signals. The Canary System is very safe because the temperature rise on the tooth surface by the laser is only 1 - 2°C, which is much lower temperature than hot beverages.

Modulated laser light hitting the tooth surface generates a thermal diffusion (heat transfer) wave. The depth that this wave can penetrate is determined by the modulation frequency. Even though its sensitivity is lower than PTR, modulated light scattering also gives information from deep inside the enamel by luminescence. The Canary System can detect suspect areas, up to a depth
of 5mm because The Canary System uses a 2Hz frequency modulation that penetrates deeper than higher frequencies (100s or 1000s Hz) and the detected PTR/LUM signals deliver integrated information from the surface to the penetration depth.

The measured PTR and LUM signals are combined into a Canary Number. As the suspicion of a carious lesion develops, the Canary Number increases. With remineralization treatment, or lesion reduction in size, the Canary Number appears to decrease.

The Canary System is associated with a photographic image of the tooth surface being examined. The images are displayed on an accompanying monitor for immediate chair-side review with the patient. Images are also shown in Canary Reports incorporating Canary Numbers and color codes for the examined teeth. The Canary software is able to record and store the Canary Numbers, images of the surfaces examined, along with the dentist's treatment recommendation.

E. Intended Use:
The Canary System is intended to be used by qualified dental professionals as an aid in the detection and monitoring of dental caries, and as an intra-oral camera to record anatomical details.

F. Indications for use:
The Canary System is indicated as an aid in the detection and monitoring of dental caries and as an intraoral camera to visualize and record anatomical details.

G. Substantial Equivalence:
Safety and effectiveness comparison to predicate devices:

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>The Canary System</th>
<th>DIAGNODent</th>
<th>SOPRO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examination of Interproximal Caries Areas</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Examination of Pit and Fissure Caries</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Smooth Surface Caries</td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Evaluation of Possible Caries Around Visible Margins of Restorations</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Evaluation of Possible Subsurface Caries lesions</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>DIAGNODent</th>
<th>SOPRO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Necessary</td>
<td>Removal of pools of</td>
<td>Clean tooth using any</td>
<td>Clean tooth using any</td>
</tr>
</tbody>
</table>

Quantum Dental Technologies: 510(k) Summary for K112139
<table>
<thead>
<tr>
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<th>SOPRO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for use</td>
<td>An aid in the detection and monitoring of dental caries and as an intraoral camera to visualize and record anatomical details</td>
<td>Aid in the diagnosis of dental caries</td>
<td>Intended to be used by qualified physicians in dentistry as an aid in the diagnosis of dental caries, and as an intraoral camera to visualize anatomical details invisible to the naked eye or with a mirror.</td>
</tr>
<tr>
<td>Core Technology</td>
<td>Combined Photothermal radiometry (PTR) and modulated luminescence (LUM) caries detection device</td>
<td>Fluorescence caries detection device</td>
<td>Light-induced fluorescence caries detection device</td>
</tr>
<tr>
<td>How suspicion of caries are detected</td>
<td>The Canary System shines a 2 Hz pulsed laser light (660nm) on the tooth surface and the device collects the converted and emitted infrared radiation (2-5μm) by heat released from the tooth (1-2 deg. C maximum increase in heat) and luminescence (715-800nm) when the laser modulates. By the interaction of the laser light with the crystalline structure of the enamel and dentin, the emitted luminescence and thermal infrared signal provide information about the health of the tooth and areas that might be suspected of having dental caries.</td>
<td>DIAGNODent emits red laser light at a wavelength of 655 nm onto a tooth surface. This wavelength causes porphyrins (coloured protein molecules) in cavous tissue to fluoresce, resulting in elevated scale readings on the display of the system. The presence of bacterial by-products is an indirect measure that caries are present.</td>
<td>SOPROLIFE emits blue LED (wavelength of 450 nm) onto a tooth surface. This wavelength excites the dentin, which, in response, reflects a light signal called fluorescence. The colour of the fluorescence signal is green when the dentin is healthy and dark red, when the dentin is infected.</td>
</tr>
<tr>
<td>How suspicion of caries are reported</td>
<td>The Canary Number is a combination of the PTR and LUM amplitude and Scale of 1 – 100 with readings below 13 suggests a healthy</td>
<td>Colour suggests health of dentin. Red suggests caries in the dentin. Green</td>
<td></td>
</tr>
</tbody>
</table>

**Pre-treatment of teeth**
- saliva using air drying
- or dabbing with cotton
- method and dry
- method

**Detection of areas of suspect Incipient**
- YES
- YES
- YES

**Target Population**
- Dentist’s Offices
- Dentist’s Offices
- Dentist’s Offices

**Printed / Electronic Report for patients and providers**
- YES
- NO
- YES

**Visual Image**
- YES
- NO
- YES
Phase readings at a point on a tooth surface. The Canary Number scale is from 0 – 100. Canary Numbers below 20 suggest a healthy tooth surface. Canary Numbers above 70 suggest the possible presence of advanced decay. Canary Numbers between 21 – 70 suggests the presence of an early lesion or decay and treatment depends upon location of these suspect areas and patient risk factors.

The stronger the red colour the larger the suspicious area of caries. Numbers below 20 suggest the presence of caries into the dentin. Numbers above 70 suggest the presence of advanced decay. Numbers between 21 – 70 suggest the presence of an early lesion or decay and treatment depends upon location of these suspect areas and patient risk factors.

<table>
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<th>SOPRO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probe</td>
<td>Lenses and mirrors</td>
<td>Fiber Optic</td>
<td>Fiber Optic</td>
</tr>
<tr>
<td>Light source</td>
<td>660 nm &lt;50 mW Laser, sinusoidally modulated at 2Hz</td>
<td>655 nm &lt;1 mw Laser</td>
<td>450 nm LED</td>
</tr>
<tr>
<td>Camera</td>
<td>CMOS</td>
<td>N/A</td>
<td>1/2'' CCD; Resolution (752x582) PAL; (768x494) NTSC</td>
</tr>
<tr>
<td>Returned light</td>
<td>AC or modulated Luminescence + thermal infrared Pulsing the laser light allow for measurement of both the luminescence and changes in thermal properties.</td>
<td>Fluorescence (DC luminescence)</td>
<td>Fluorescence (DC luminescence)</td>
</tr>
<tr>
<td>Detectors for Returned Light</td>
<td>• Photodiode for LUM and or AC Fluorescence • Mid-IR detector for PTR • Visible Range CMOS Camera to track area scanned &amp; visual surface changes</td>
<td>Photodiode for DC fluorescence</td>
<td>Visible range CMOS camera for DC fluorescence</td>
</tr>
<tr>
<td>Sterilization and Disinfection</td>
<td>Disposable, one-time use plastic sleeve and plastic tip. The Canary System unit and cables can also be disinfected with alcohol-based solutions.</td>
<td>Probe tip only, autoclave</td>
<td>Probe autoclave</td>
</tr>
<tr>
<td>Medical Device Classification</td>
<td>II</td>
<td>II</td>
<td>II</td>
</tr>
<tr>
<td>User interface</td>
<td>• Graphical, numeric and audible tones.</td>
<td>Numeric and audible tones LED numbers</td>
<td>Image with colours</td>
</tr>
</tbody>
</table>

Quantum Dental Technologies: 510(k) Summary for K112139
The Canary System is substantially equivalent to other legally marketed devices in the United States. This conclusion is based on indications for use, bench, in vitro studies, as well as EMC, laser and electrical safety testing. Differences that exist between The Canary System and the predicate devices relating to technical operation and performance do not affect the safety and effectiveness of the device.
Quantum Dental Technologies, Incorporated  
Josh Silvertown, Ph.D, M.B.A.  
Vice President, Corporate Development  
748 Briar Hill Avenue  
Toronto, Ontario  
Canada M6B 1L3

Re: K112139  
Trade/Device Name: The Canary System™  
Regulation Number: 21 CFR 872.1745  
Regulation Name: Laser Fluorescence Caries Detection Device  
Regulatory Class: II  
Product Code: NBL  
Dated: October 9, 2012  
Received: October 10, 2012

Dear Dr. Silvertown:  

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" (21 CFR 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,

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): K112139

Device Name: The Canary System™

Indications for Use:
The Canary System is intended to be used by qualified dental professionals as an aid in the diagnosis of dental caries, and as an intra-oral camera to visualize and record anatomical details.

Prescription Use X AND/OR Over-the-counter Use NO
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K112139