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## Section 5 - 510(k) Summary (continued)

**6. Characteristics of the device in comparison to those of the predicate device(s)**

**Lubricant Comparison:**

Both the ClearView™ Dental Handpiece Lubricant and the Phase Change Dental Lubricant are liquids demonstrated to be suitable for lubrication of dental handpieces. They are both considered completely safe under normal usage and have no expected hazards.

**Lubricator Comparison:**

Both the ClearView™ and the Assistina have a reservoir for lubricant, a cover to contain exhaust, a method of connecting handpieces, push button operation, a hose and connection to a pressurized air supply. Both devices use pressurized air for power and do not have electrical components. **Both devices lubricate dental handpieces; however, the ClearView™ does not spray cleaner through the chip air and water line as does the Assistina.** The fact that the ClearView™ does not spray cleaner through the chip air and water line does not affect the safety and efficacy of the ClearView™ Dental Handpiece Lubricator for its intended use of lubricating handpieces.

**7. Safety and Performance:**

The difference between the ClearView™ Dental Handpiece Lubricator and Lubricant and the above mentioned predicate devices do not raise any questions regarding the safety and effectiveness of the lubricator or lubricant. The ClearView™ Dental Handpiece Lubricator employs the same technological characteristics to support the intended use of lubricating air-driven dental handpieces with rotating turbines and purge old lubricant for the purpose of maintenance prior to sterilization as the W & H Assistina. In addition, the ClearView™ Dental Handpiece Lubricant and the predicate device, the Phase Change Dental Lubricant, are commonly used in equipment with incidental food contact. The devices, as designed, are as safe and effective as their predicate devices.

**8. Conclusion**

Based on the design, material, function and intended use discussed herein, Dental Air Solutions of NC, Inc., believes the ClearView™ Dental Handpiece Lubricator and Lubricant is substantially equivalent to predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act.

## Section 5 - 510(k) Summary

**1. Applicant Contact:**

Thomas K. Fee, President
Dental Air Solutions of NC, Inc.
224 Branchside Lane
Holly Springs, NC 27540
Phone: 919-771-7545
Fax: 919-762-9070
Email: tomf@dentalairsolutions.com

**Date Prepared:** November 17, 2006

**2.**

| | |
|---|---|
| **Name of Device:** | ClearView™ Dental Handpiece Lubricator and Lubricant |
| **Common Name:** | Dental Handpiece Accessory (maintenance, lubrication) |
| **Classification Name:** | Accessory to Dental Handpiece, Class I medical device<br>Regulation 21 CFR 872.4200,<br>Product Code EFB |

**3. Identification of device(s) to which the submitted claims equivalence:**

The ClearView™ Dental Handpiece Lubricator and Lubricant is substantially equivalent to the following predicate devices:

a. Predicate for Lubricator:
- W & H Assistina, 510(k) K010127

b. Predicate for Lubricant:
- Phase Change Dental Lubricant, 510(k) K954991

**4. Device Description:**

**Lubricator**: This information is detailed on the manufacturing drawings and photographs included in the body of this submission.

**Lubricant**: ClearView™ Dental Handpiece Lubricant is a liquid lubricant specifically intended for use with the ClearView™ Dental Handpiece Lubricator for the purpose outlined above. Detailed information is contained in the body of this submission.

**5. Intended Use of the Device:**

The ClearView™ Handpiece Lubricator is used for the delivery of ClearView™ Handpiece Lubricant to air driven dental handpieces, turbines and air motors for the purpose of maintenance prior to sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dental Air Solutions of North Carolina, Incorporated
C/O Mr. Jeff D. Rongero
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
Research Triangle Park, North Carolina 27709-3995

FEB 5 2007

Re: K070297
Trade/Device Name: ClearView™ Dental Handpiece Lubricator and Lubricant
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: January 24, 2007
Received: January 31, 2007

Dear Mr. Rongero:

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,

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

## Section 4 - Indications for Use Statement

510k number if known: K070297

Device Name: ClearView™ Dental Handpiece Lubricator and Lubricant

Indications for Use:

The ClearView™ Handpiece Lubricator is used for the delivery of ClearView™ Handpiece Lubricant to air driven dental handpieces, turbines and air motors for the purpose of maintenance prior to sterilization.

Prescription Use √ (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 OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K070297