K072554

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Sable Industries
Fiber Optic High Speed Dental Handpieces & Accessories

I. Submitter Information

510(k) Owner:
Sable Industries, Inc.
100 Campbell Avenue, Suite 5
Kitchener, Ontario N2H 4X8
Canada

NOV 1 4 2007

Contact Person:
Jacob Jagt – QA Manager
(519) 579-9323 (office)
(519) 579-9324 (fax)

United States Agent / U.S. Consultant:
Kevin Randall – President
GlobalReg Compliance Associates, Inc.
581 Whiles Court
Erie, CO 80516
(303) 956-8595 (direct)
(303) 828-0835 (fax)
Email: kevin@globalregcompliance.com

Date Summary Prepared:
September 4, 2007

II. Name of Device

- Trade Name: Access™ L & KL and RotaMax™ L & KL Fiber Optic High Speed Dental Handpieces & Accessories
- Common Name: Fiber Optic High Speed Dental Handpieces & Accessories
- Classification Name: Handpiece, Air-Powered, Dental

III. Predicate Devices

Subject Device	Predicate Device(s)
Access™ L & KL Fiber Optic High Speed Dental Handpiece	Bien-Air Prestige L & LK Turbine Handpiece (**K983183**)
RotaMax™ L & KL Fiber Optic High Speed Dental Handpiece	Bien-Air Bora L & LK Turbine Handpiece (**K983183**)

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IV. Device Description & Technological Characteristics

The Access™ L & KL and RotaMax™ L & KL Fiber Optic High Speed Dental Handpieces and Accessories are indicated for use in the preparation of dental cavities for restorations, such as fillings. These handpieces are a series of fiber optic high speed, air-driven turbine handpieces for use with standard size burs in accordance with ISO 1797. The technological characteristics and form/fit/function of the Access™ L & KL and RotaMax™ L & KL handpieces, respectively, are substantially equivalent to the Bien-Air Prestige L & LK Turbine Handpieces (FDA-cleared via K983183) and the Bora L & LK Turbine Handpieces (FDA-cleared via K983183).

The Access™ series have a stainless steel ball bearing turbine with rotational speeds of up to 335,000 rpm and a smaller head as compared to the RotaMax™ models. The Access™ is available for use with a Sable 6 Hole, 360° Swivel Quick Connect Coupler or Multiflex™ Coupler. The handpiece also contains a triple spray cooling system. The three air and water ports are located within the detachable diffuser. The diffuser is replaceable and is easily removed for cleaning. The Access™ incorporates an anti-retraction valve within the handle. The handpiece is autoclavable to 135° C. The Access™ has a patented non-heating, push button chuck bur-changing mechanism. The dual glass optics consist of a single block of optic rods. The glass rods are angled to help reduce shadows on the tooth. The fiber-optic light unit is fully interchangeable.

The RotaMax™ series have a ball bearing turbine with rotational speeds of up to 310,000 rpm and a larger head as compared to the Access™ models. The RotaMax™ is available for use with a Sable 6 Hole, 360° Swivel Quick Connect Coupler or Multiflex™ Coupler. The handpiece also contains a triple spray cooling system. The three air and water ports are located within the detachable diffuser. The diffuser is replaceable and is easily removed for cleaning. The RotaMax™ incorporates an anti-retraction valve within the handle. The handpiece is autoclavable to 135° C. The RotaMax™ also has a patented non-heating, push button chuck bur-changing mechanism. The dual glass optics consist of a single block of optic rods. The glass rods are angled to help reduce shadows on the tooth. The fiber-optic light is fully interchangeable.

The electronic fiber optic control board available for use with the Access™ and RotaMax™ series handpieces is for one or two handpieces and supplies an adjustable power output ranging from 2 - 3.5 volts. The control board has an adjustable illumination time delay ranging from 0.5 - 4.5 seconds for each handpiece.

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A range of air hoses are available for use with the Access™ and RotaMax™ series handpieces. The connectors for these hoses meet the criteria either for Type B or C per ISO 9168, and therefore have five outlets (to accommodate drive-air & exhaust, fiber optic, spray-air, and irrigation) or four outlets plus electrical contacts (to accommodate drive-air & exhaust, fiber optic power supply, spray-air, and irrigation). The air hoses are straight and come in various colors.

KaVo Spray (preamendments device) or other FDA-cleared lubricants may be used to lubricate the Access™ L & KL and RotaMax™ L & KL Fiber Optic High Speed Dental Handpieces.

V. Intended Use

Sable Industries *Fiber Optic High Speed Dental Handpieces & Accessories* are indicated for the preparation of dental cavities for restorations, such as fillings.

VI. Non-Clinical Performance/Safety Data

The performance and safety of the Sable Industries *Fiber Optic High Speed Dental Handpieces & Accessories* are based upon conformity with applicable aspects of the following standards:

- ISO 7785-1 High-speed Air Turbine Handpieces
- ISO 9168 Dental Handpieces – Hose Connections
- ISO 1797-1 Dental Rotary Instruments – Shanks
- ISO 11134 Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization
- ISO 10993 Biological Evaluation of Medical Devices Part-1: Evaluation and Testing
- IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for safety
- IEC 60601-1-2 Medical Electrical Equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and test.

Conformity with the above standards demonstrates that the Sable Industries *Fiber Optic High Speed Dental Handpieces & Accessories* are as safe, as effective, and perform as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2007

Sable Industries, Incorporated
C/O Mr. Kevin Randall
President
GlobalReg Compliance Associates, Incorporated
581 Whiles Court
Erie, Colorado 80516

Re: K072554
Trade/Device Name: Fiber Optic High Speed Dental Handpieces & Accessories
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: September 4, 2007
Received: September 10, 2007

Dear Mr. Randall:

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

510(k) Number (if known): K027554

Device Name:

Fiber Optic High Speed Dental Handpieces & Accessories

Indications For Use:

Sable Industries *Fiber Optic High Speed Dental Handpieces & Accessories* are indicated for the preparation of dental cavities for restorations, such as fillings.

PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use**_____

(Optional Format 1-2-96)

Susan Ryan

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

510(k) Number: K027554