

K08301

# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Sable Industries

Premium Slow Speed Dental Handpieces & Accessories

FEB 23 2009

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## I. Submitter Information

**510(k) Owner:** Sable Industries, Inc.  
100 Campbell Avenue, Suite 5  
Kitchener, Ontario N2H 4X8  
Canada  
Establishment Registration: 3002105090

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

**United States Agent / U.S. Consultant:** GlobalReg Compliance Associates, Inc.  
16576 W. 53<sup>rd</sup> Way  
Golden, CO 80403  
(303) 956-8595 (direct)  
(303) 828-0835 (fax)  
Email: info@globalregcompliance.com

**Date Summary Prepared:** October 6, 2008

## II. Name of Device

- Trade Name: Premium Slow Speed Dental Handpieces & Accessories
- Common Name: Air-Powered Dental Handpieces & Gear-Driven Attachments
- Classification Name: Dental Handpiece & Accessories

## III. Predicate Devices

Subject Device	Predicate Device(s)
Premium Slow Speed 20K Air Motor w/ Internal Air & Water (p/n 1610101)	Bien Air Low Speed Motors (K983183)
Slow Speed & Premium Slow Speed Heads Ball Bearing Switch Latch (p/n 1610801)	Bien Air Straight and Contra- Angle Handpieces (K983183)

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Subject Device	Predicate Device(s)
Slow Speed & Premium Slow Speed Heads Ball Bearing Push Button (p/n's 1610802, 1600411, 1600508)	Bien Air Straight and Contra-Angle Handpieces (K983183)
Premium Slow Speed Contra-Angles 1:1 Fiber Optic Ball Bearing w/ Internal Air & Water (p/n 1610299)	Bien Air Straight and Contra-Angle Handpieces (K983183)
Premium Slow Speed Contra-Angles 1:1 Ball Bearing w/ Internal Air & Water (p/n 1610201)	Bien Air Straight and Contra-Angle Handpieces (K983183)
Premium Slow Speed Straight Nosecones 1:1 Ball Bearing w/ Internal Air & Water (p/n 1610301)	Bien Air Straight and Contra-Angle Handpieces (K983183)

#### IV. Device Description & Technological Characteristics

##### A. Premium Slow Speed 20K Air Motor w/ Internal Air & Water:

The Sable Premium Slow Speed Air Motor is used in conjunction with accessories such as contra-angle and straight attachments that are manufactured in accordance with ISO 7785-2. This premium slow-speed air-driven motor is capable of running up to a speed of 20,000 RPM at 43.5 PSI (3 Bar). It does not require a separate coupler and interfaces with Midwest-type 4-hole tubing. The motor has an integrated locking mechanism for easy connection and removal of any attachment. The motor can deliver both chip air and water to assist with the removal of debris from the cutting area in the oral cavity when used in conjunction with an ISO designed attachment with internal air and water lines.

##### B. Slow Speed & Premium Slow Speed Heads (push button and switch latch)

The Sable Premium Slow Speed Heads are used in conjunction with attachments (contra-angles and straight) and slow speed motors manufactured in accordance with ISO 7785-2 and ISO 13294, respectively. These heads have an integrated locking mechanism for easy connection and removal of any attachment. These heads can be used with a variety of different latch burs conforming to the specifications of ISO 1797-1. These heads are capable of running up to a speed of 40,000 RPM at 42 PSI (3 Bar) and have a 1:1 gear/drive ratio. These heads may be used with attachments capable of delivering both chip air and water when used in conjunction with an ISO-designed air or electric motor with internal air and water.

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#### C. Premium Slow Speed Contra-Angles (1:1 Fiber Optic and Non-Fiber Optic Ball Bearing w/ Internal Air & Water):

The Sable Premium Slow Speed Contra-Angles are used in conjunction with components such as slow speed heads and slow speed motors manufactured in accordance with ISO 7785-2 and ISO 13294, respectively. The fiber optic version produces 25,000 LUX for a shadow-less view of the oral cavity. These contra-angles have an integrated locking mechanism for easy "snap-on" connection and removal from the motor. These contra-angles can be used with Sable premium slow speed heads which are attached / removed by a "quick-twist" locking mechanism on the contra angle. These contra-angles are capable of running up to a speed of 40,000 RPM at 43.5 PSI (3 Bar) and have a 1:1 gear/drive ratio. These contra-angles deliver both chip air and water when used in conjunction with an ISO-designed air or electric motor with internal air and water.

#### D. Premium Slow Speed Straight Nosecones (1:1 Ball Bearing w/ Internal Air & Water):

The Sable Premium Slow Speed Straight Nosecones are used in conjunction with slow speed motors manufactured in accordance with ISO 13294. These nosecones have an integrated locking mechanism for easy connection and removal from the motor and can be used with a variety of different burs conforming to the specifications of ISO 1797-1. These nosecones are capable of running up to a speed of 40,000 RPM at 42 PSI (3 Bar) and have a 1:1 gear/drive ratio. These nosecones deliver both chip air and water when used in conjunction with an ISO-designed air or electric motor with internal air and water.

#### V. Intended Use

Sable Industries *Premium Slow Speed Dental Handpieces & Accessories* are indicated for use in general dentistry for cleaning and polishing of teeth.

#### VI. Non-Clinical Performance/Safety Data

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

- ISO 13294 Dental Handpieces – Dental Air Motors
- ISO 7785-2 Dental Handpieces -- Part 2: Straight & Geared Angle Handpieces

## **510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Sable Industries**

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- ISO 9168 Dental Handpieces – Hose Connections
- ISO 3964 Dental Handpieces – Coupling Dimensions
- ISO 17665-1:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11134 Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization
- ISO 10993-1 Biological Evaluation of Medical Devices Part-1: Evaluation and Testing

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

**END OF 510(K) SUMMARY**

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Sable Industries, Incorporated  
C/o Mr. Kevin Randall  
President  
GlobalReg Compliance Associates, Incorporated  
16576 West 53<sup>rd</sup> Way  
Golden, Colorado 80403

**FEB 23 2009**

Re: K083101  
Trade/Device Name: Premium Slow Speed Dental Handpieces and Accessories  
Regulation Number: 21 CFR 872.4200  
Regulation Name: Dental Handpiece and Accessories  
Regulatory Class: I  
Product Code: EFB, EGS  
Dated: January 27, 2009  
Received: February 20, 2009

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.

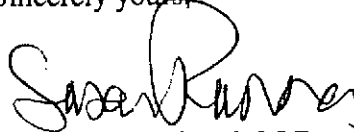
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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,



Ginette Y. Michaud, M.D.

Acting 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): K083101

Device Name:

**Premium Slow Speed Dental Handpieces & Accessories**

**Indications For Use:**

Sable Industries *Premium Slow Speed Dental Handpieces & Accessories* are indicated for use in general dentistry for cleaning and polishing of teeth.

**PLEASE DO NOT WRITE BELOW THIS LINE  
CONTINUE ON ANOTHER PAGE IF NEEDED**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use  OR Over-The-Counter Use

Soren Pines

**(Optional Format 1-2-96)**

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

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510(k) Number: K083101