OCT 2 0 2004

K042759

SECTION 15: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

15.1 SUBMITTER INFORMATION

a. Company Name:	Bien Air
b. Company Address:	Langasse 60 Case postale 6008 2500 Bienne 6. Switzerland
c. Company Phone: Company Facsimile:	(011) 41 32 344 64 64 (011) 41 32 344 64 91
d. Contact Person:	Alain Leonetti Regulatory Affairs & Quality Manager
e. Date Summary Prepared:	October 19, 2004

15.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	OPTIMA MX
b. Classification Name:	Operative Dental Unit 21 CFR 872.6640
c. Common Name:	Operative Dental Unit

15.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Sirona Dental Systems	SiroTorque L	K031584	08/19/2003

15.4 DEVICE DESCRIPTION

The Optima MX dental unit for use in dental restoration, phophylaxis and endodontic procedures. The Optima MX is composed of a power supply, control unit, hose and a brushless micromotor. The control unit is a programmable unit that controls the torque, speed and clockwise or counterclockwise rotation of the motor. The inputs to the control unit are supplied by a color touchscreen on the

Optima MX. Inputs can also be made by the foot pedal of the treatment center through the pneumatic outlet. The micromotor is a brushless motor with 4 quadrant speed control. The micromotor has a rotation speed of 100 – 40,000 rpm and can be rotated in a clockwise or counterclockwise direction.

15.5 INTENDED USE

The OPTIMA MX is intended for use in dentistry for restoration, phophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output from a dental treatment center.

15.6 TECHNOLOGICAL CHARACTERISTICS

The OPTIMA MX is composed of a control unit, power supply, hose and micromotor. Performance testing was conducted to validate the safety and effectiveness of the OPTIMA MX and included electrical safety, electromagnetic compatibility and validation and verification testing of the software functions. Testing was conducted in accordance with recognized consensus standards.

	BIEN AIR (Proposed)	SIRONA DENTAL SYSTEMS K031584
Device	OPTIMA MX	SIROTORQUE L
Indications for Use	The Optima MX is intended for use in dentistry for restoration, phophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output from a dental treatment center.	The SiroTorque L is intended to convert pneumatic output from a dental treatment center to electrical energy for operation of electrically-driven dental handpieces
Device Components	Control unit with hose and electrical motor	Control unit with hose and electrical motor
Speed Range	100 – 40,000 rpm	2,000 – 40,000 rpm
Torque	3 Ncm maximum	2.4 Ncm maximum
Rotation	Clockwise, counterclockwise	Clockwise, counterclockwise
Light	Variable intensity	Variable intensity
Cooling Air Requirements	25 Nl/min	30 Nl/min
Spray Air Pressure	36 psi (2.5 bar	39 psi (2.7 bar)
Spray Water Pressure	29 psi (2 bar)	29 psi (2 bar)
Motor Length	69 mm	60 mm
Motor Diameter	21.2 mm	21 mm

15.7 PERFORMANCE TESTING

Performance testing of the OPTIMA MX was conducted to evaluate the rotational speed and torque measurements of the device. This testing was done in comparison to the predicate device, the SiroTorque. Results of the testing showed that the both devices had good control of speed with the OPTIMA MX being slightly better at lower speeds. Torque curves were developed for the tow devices and they were found to share a similar trend. Compared to the theoretical curve, both devices showed a slightly lower torque in the upper range and slightly more torque in the lower range.

15.8 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission. Performance and software evaluations of the OPTIMA MX show that the device performs as intended. Comparison of the OPTIMA MX to the predicate device show that the device is substantially equivalent.

The OPTIMA MX is substantially equivalent to the SiroTorque L based on equivalence of the intended uses, comparison testing and technical characteristics. The OPTIMA MX and the SiroTorque were comparison tested for rotational speed and torque measurement. Both devices were shown to be comparable in speed and torque values.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2004

Bien-Air SA Switzerland
C/O Ms. Erin Sparnon
Responsible Third Party Official
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K042759
Trade/Device Name: Optima MX
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: October 4, 2004
Received: October 5, 2004

Dear Ms. Sparnon:

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.

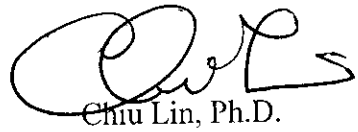
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

INDICATION FOR USE

510(k) Number: K042759

Device Name: Optima MX

Indications for Use:

The Optima MX is intended for use in dentistry for restoration, phophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output from a dental treatment center.

Prescription Use ___X___ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K042759