K031584

AUG 19 2003

510(k) Summary
for
Sirona Dental Systems
SiroTorque L

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 32 94

Date Prepared: May 1, 2003

2. Device Name

Proprietary Name:	SiroTorque L
Common/Usual Name:	Energy conversion and controller unit
Classification Name:	Dental Handpiece and Accessories

3. PREDICATE DEVICES

Bell International Mark 20 and Mark 25 Hand Engine Controller (K964860)

4. INTENDED USE

The SiroTorque L is intended to convert pneumatic output from a dental treatment center to electrical energy for operation of electrically-driven dental handpieces.

5. DEVICE DESCRIPTION

The SiroTorque L is composed of a supply / control unit, supply hoses, connection cables, a transformer and two alternative electric micromotors. The pneumatic outlet from the dental treatment unit, which would be the supply hose for an air-driven instrument (e.g., a high speed handpiece or an air motor), provides the input to the SiroTorque L supply / control unit. The electronic circuitry within the SiroTorque L

converts the air pressure input to an electrical signal, which is output to the supply hose for the handpiece electric micromotor.

The handpiece electric micromotor is activated using the footswitch of the existing dental operative unit. As the footswitch is pressed farther down, the pressure of the compressed air supply increases, which in turn increases the rotational speed of the micromotor. The permissible speed range is adjustable by the user from 1,000 to 40,000 rpm, although the highest speeds are only attainable if the compressed air supply has a pressure of at least 3 bars. The minimum and maximum speeds are displayed and can be adjusted using the SiroTorque L control panel.

The SiroTorque L also provides the user with the following features:

- Selection of clockwise and counter-clockwise rotation of the dental handpieces
- Variable intensity handpiece light
- "Satellite" version: The control panel of the SiroTorque L can be separated from the supply / control unit and mounted so as to be more easily accessible for the user

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The SiroTorque L is substantially equivalent to the Bell International Mark 20 and Mark 25 Hand Engine Controller based on equivalence of the intended uses and technical characteristics. Performance testing to validate the safety and effectiveness of the SiroTorque L included electrical safety, electromagnetic compatibility, and validation testing of both hardware and software functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2003

Sirona Dental Systems GmbH
C/O Mr. Donald J. Sherratt
Responsible Third Party Official
Intertek Testing Service
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K031584
Trade/Device Name: SiroTorque L
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: August 4, 2003
Received: August 6, 2003

Dear Mr. Sherratt:

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.

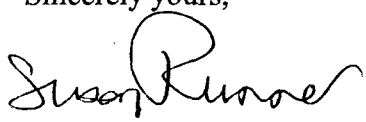
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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,



Susan Runner, DDS, MA
Interim 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):

Device Name: SiroTorque L

Indications for Use:

The SiroTorque L is intended to convert pneumatic output from a dental treatment center to electrical energy for operation of electrically-driven dental handpieces.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K031584

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)