MAR 3 1 2006

510(k) Summary
for
Sirona Dental Systems
SiroEndo

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany

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

Date Prepared: November 14, 2005

2. DEVICE NAME

Proprietary Name:	SiroEndo
Common/Usual Name:	Dental root canal measurement and treatment device
Classification Names:	Dental Handpiece and Accessories and Root Apex Locator

3. PREDICATE DEVICE

Morita DENTAPORT ZX (K031204)

4. INTENDED USE

The SiroEndo is intended for dental root canal length measurement and root canal treatment.

5. DEVICE DESCRIPTION

The SiroEndo is an electronic digital control system indicated for endodontic treatment that allows a dentist to locate the anatomical root canal apex and to obtain root canal length measurements. The SiroEndo system is comprised of the central unit mounted via a support arm to a dental unit, micromotor, foot pedal and power supply. The central unit electronically controls the micromotor's rotation speed, rotation direction and torque. A commercially available handpiece is attached to the micromotor.

Systems of files are selectable with corresponding preset values for rotation speed and torque that are adjusted according to the entered handpiece reduction ratio. Individual values of rotation speed and torque can be entered and saved. File systems with individual values of rotation speed and torque can be stored in an internal memory or on a SiroEndo memory stick and can be re-called. The SiroEndo incorporates a selectable auto-stop and auto-reverse function triggered when the selected torque has been reached.

The SiroEndo offers a selectable apex locator feature that makes the distance between file tip and apex visible. The motor stops, if programmed, when the apex has been reached.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The SiroEndo is substantially equivalent to the Morita DENTAPORT ZX (K031204) based on equivalence of the intended use, similar features and technical characteristics. Performance testing to validate the safety and effectiveness of the SiroEndo 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

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Sirona Dental Systems GMBH
C/O Ms. Mary McNamara-Cullinane
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760-4153

Re: K052515
Trade/Device Name: SiroEndo
Regulation Number: 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: I
Product Code: EKX
Dated: March 16, 2006
Received: March 17, 2006

Dear Ms. McNamara-Cullinane:

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 (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.

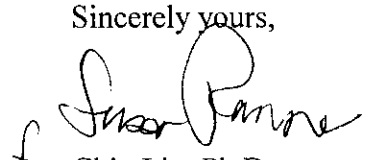
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for 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

INDICATIONS FOR USE

510(k) Number (if known): 052515

Device Name: SiroEndo

Indications for Use:

The SiroEndo is intended for dental root canal length measurement and root canal treatment.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] General Hosp...
[illegible] Dental Devices

K052515