DEC 11 1998

510(k) Summary
for
Sirona C8

K983242

## 1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim, Germany

Contact Person: Walter Schneider
Telephone: 49 625 1162 778

Date Prepared: September 14, 1998

## 2. DEVICE NAME

Proprietary Name: Sirona C8
Common/Usual Name: Dental Operative Unit
Classification Name: Dental Operative Unit with Accessories

## 3. PREDICATE DEVICES

Pelton & Crane's Spirit S1 - K962071

## 4. DEVICE DESCRIPTION

The Sirona C8 Dental Operative Unit and Accessories consist of the following components:

- Treatment Chair
- Dentist's Element which controls the pressure for the air and water, spray and drive adjustments for the instruments which can also be controlled by a foot pedal, and control of the optional Cuspidor feature

- Assistant's Element with Cuspidor, controls automatic and manual air vacuum and suction
- Dental Lamp

## 5. INTENDED USE

The Sirona C8 is an electronically controlled dental operative unit with accessories that are intended to supply power to, and serve as a base for dental devices and accessories.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The general components, design, characteristics, and mode of operation of the Sirona C8 Dental Operative Unit and Accessories are substantially equivalent to Pelton & Crane's Spirit S1 Dental Systems. Both are AC powered dental operative units with accessories that are intended to supply power to, and serve as a base for dental devices and accessories. Both Dental Systems include a treatment chair, the Dentist's Element, the Assistant's Element and a Dental Light, offer several additional options and electronically control chair movements and water unit functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 1998

Sirona Dental Systems GmbH & Company KG
C/O Ms. Sheila Hemeon-Heyer
Senior Consultant
Medical Device Consultant, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K983242
Trade Name: Sirona C8 Dental Operative Unit with Accessories
Regulatory Class: I
Product Code: EIA
Dated: September 14, 1998
Received: September 16, 1998

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Patricia Cucinotta for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Sirona C8

Indications For Use:

This product is a Dental Operative Unit with accessories that is intended to supply power to, and serve as a base for dental devices and accessories. This product includes a dental chair. The unit is intended for use in the dental clinic environment and used by trained dentists and/or dental technicians and assistants.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Gerald Shupp

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983242

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

(Optional Format 1-2-96)