5.0 510(K) SUMMARY

K070196

The 510(k) Summary follows.

510(k) SUMMARY

JAN 26 2007

Manufacturer's Name, Contact Person, Address, Phone, Fax, Email, Date Prepared

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Contact Name:	Jim Ronalds
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Date Prepared: September 14, 2006, 2006

Device Name, Common/Generic Name and Classification Name

Proprietary Name: Flight Dental Systems A-Series Dental Operative Unit

Common/Usual Name: Dental operative unit

Classification Name / Code: Unit, Operative Dental / EIA

Predicate Device

Sirona C8+ Dental Operative unit – K983242

Description of the Device

The Flight A-Series Dental Operative Unit is a dental operating system. The device includes a patient chair, dentist's element, utility center and a floor box. The unit may also include a cuspidor, an assistant's element and a dental operating light. The doctor's element may be mounted on the patient chair or on a mobile cart.

The unit is used to position the patient in a comfortable position and to provide the power to the dentist's instruments including dental handpieces.

Intended Use of the Device

The Flight Dental Systems A-Series Operative Units are intended to supply power and serve as a base for dental devices and accessories. The use intended is in the treatment of dental patients in

the dental clinic/office environment. The units are for use only by trained dentists, dental hygienists, dental technicians and dental assistants.

Technological Characteristics

The general components, design, characteristics and mode of operation of the Flight A-Series Dental Operative Unit is substantially equivalent to Sirona C8 Dental Operative Unit. Both are AC powered operative units with accessories that are intended to supply power to and serve as a base for dental devices and accessories. Both systems include the doctor's element, patient chair, floor box and utility center and may include optional cuspidors, operating lights and assistants elements.

Performance Data

Bench testing has been performed on a sample that is in all respects the same as the device to be marketed. Testing was performed against local GB standards in China including GB9706.1-1995 and YY/T1043-2004 which are near equivalent to the recognized consensus standards ISO 7494-2:2003 and ISO 7494-1:1996. In any case in which the local standard was not equivalent to the recognized Consensus standard, additional testing has been performed in accordance with the recognized consensus standards.

Further independent laboratory testing was performed by Intertek Testing of Mississauga, Ontario Canada to confirm conformity UL 60601-1 and CAN/CSA-C22.2 No. 601.1 M90 and with the electrical safety portions of ISO 7494-1:1996. In any case in which the local standard was not equivalent to the recognized Consensus standard, additional testing has been performed in accordance with the recognized consensus standard.

The equipment has also been tested against ISO 9168:1991, and found to be in compliance with the standard. The patient and operator contact surfaces have been tested and found to be in compliance with ISO 7405:1997. The device is composed of materials that have a long history of use in the medical and dental community.

No deviations from the recognized standards were found except those noted in the table provided in section 9 of this submission. In any case of deviation from the recognized standard alternate methods of meeting safety and effectiveness requirements were implemented.

The conclusions drawn from the bench testing are that the device is as safe and as effective as the predicate device. Furthermore, the device performs its intended tasks as well as or better than the legally marketed predicate device and complies with the recognized standards.

Substantial Equivalence Conclusions

In all important respects the Flight dental Systems A-Series Dental Operative Units are substantially equivalent to the Sirona Dental Systems C8 (K983242). This conclusion is based upon indications for use, technical characteristics, device users and features comparison. Any

differences in the technological characteristics do not raise any new safety and effectiveness issues.

Characteristic	Sirona C8 - K983242	Flight Dental Systems A-Series
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	Equivalent
Control of Air and Water	Uses pneumatically controlled vales to control the flow of air and water. On/off and intensity controlled by foot pedal	Equivalent
Installation	Available with chair mounted and cart mounted dentist element. Installed by trained technicians.	Equivalent.
Components	Doctors element, assistant's element, flex arm, utility center with optional cuspidor, patient chair, treatment light, floor box.	Equivalent
Optional accessories	Cuspidor, Assistant element with vaccum valves, treatment light, foot switches, monitor mounts	Equivalent
Power and Utility Supply	110V/220V AC electrical supply, compressed air and water	Equivalent
Compatibility	Compatible with industry standard fittings for Air/water syringe tips, high speed and low speed pneumatic turbines, air scaler, air polisher, High Volume Evacuator tips. Use industry standard 4-Hole handpiece tubings.	Equivalent
Electrical Safety Standards	Not Specified	UL 60601-1 CAN/CSA-C22.2 No. 601.1 M90 See Appendix H
Water System	User may select Self Contained water system or city water supply	Equivalent
Cleaning System	Water Flush	Equivalent -- See Appendix E
Activation	Master on/off, toggle switch and foot control	Equivalent
Place of Use	Dental office, hospital	Equivalent
Intended Users	Dentists, Dental Hygienists, Dental Assistants	Equivalent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 6 2007

HR Dental Products, Incorporated
C/O Mr. Neil E. Devine
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K070196
Trade/Device Name: Flight Dental Systems A-Series Dental Operative Units
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: January 19, 2007
Received: January 22, 2007

Dear Mr. Devine:

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/industry/support/index.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

Indications for Use

510(k) Number: K070196

Device Name: Flight Dental Systems A-Series Dental Operative Units

Indications for Use:

Statement of Indication for Use

The Flight Dental Systems A-Series Operative Units are intended to supply power and serve as a base for dental devices and accessories. The use intended is in the treatment of dental patients in the dental clinic/office environment. The units are for use only by trained dentists, dental hygienists, dental technicians and dental assistants.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulay for MSR

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

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