NOV - 1 2005

K052470

EXHIBIT 2

510(k) Summary

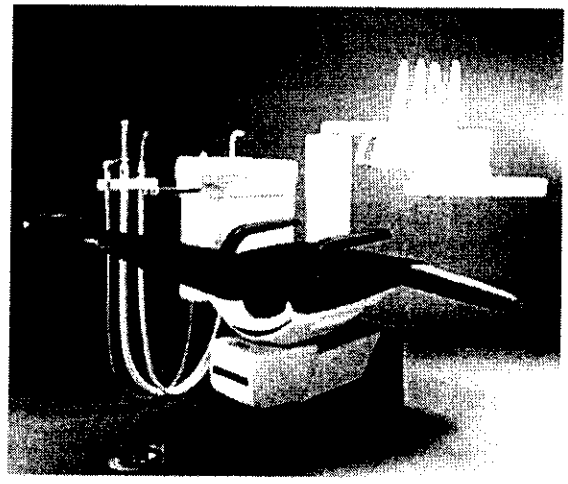
Shanghai Fimet Medical Instrument Co., Ltd.
961 Kangqiao Road, Pudong,
Shanghai 201315 China
Tel: +86 21 58120997
Fax: +86 21 58120780
E-mail: fimet@fimet.com.cn
Contact: Simo Makkonen, General Manager
October 26, 2005

1. Identification of the Device:
   Proprietary-Trade Name: F1 Series Dental Chairs with Operative Unit
   Classification Name: Unit, operative dental Product Code EIA
   Common/Usual Name: Dental operative unit and accessories

2. Equivalent legally marketed device: Sirona Dental Systems C8+ , K032543 .

3. Indications for Use (intended use): The F1 Series Dental Chairs with Operative Unit 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/office environment and used by trained dentists and/or dental technicians and assistants.

4. Description of the Device: F1 Series Dental Chairs with Operative Units provide patient comfort and dentists' air and water supplies for dental instruments and procedures. Water pressure: 200~400Kpa. Air pressure: 600~800Kpa. The units can be powered from ~110/220/230V. The chair is motorized. The system is compatible with instruments from various manufacturers with standard fittings.



5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	Sirona Dental Systems C8+ , K032543	Shanghai Fimet F1 Series Dental Chairs with Operative Unit
Indications for use	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/office environment and used by trained dentists and/or dental technicians and assistants.	SAME
Power	100/120/240 ac	SAME
Components	Chair, dentist instrument board, cuspidor, assistants board, dental light, footswitches	SAME
Compatibility	Air water syringe, high and low speed turbines, electric motors, ultrasonic scalers, fiber optic instruments, dental curing light, water warmer, airscaler, air polisher	SAME
Safety Standards	Not specified	UL Standard for Safety, Medical Devices, UL 60601-1

6. Conclusion: In all important respects, the F1 Series Dental Chairs with Operative Units are substantially equivalent to the Sirona Dental Systems C8+ , K032543. This conclusion is based on indications for use, feature comparisons, and safety standards testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Shanghai Fimet Medical Instrument Company Limited
C/O Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K052470
Trade/Device Name: F1 Series Dental Chairs with Operative Unit
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: September 6, 2005
Received: September 12, 2005

Dear Mr. Kamm:

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

K052470

Indications for Use

510(k) Number (if known):

Device Name: F1 Series Dental Chairs with Operative Unit

Indications For Use:

The F1 Series Dental Chairs with Operative Unit 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/office environment and used by trained dentists and/or dental technicians and assistants.

Prescription Use X AND/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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K052470