APR - 4 2008

K080438

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: _____

1. Applicant Device Information

Trade/Proprietary Name: Dental Unit with Chair
Model: S2300, S2305, S2308, S2315, S2318, S2320
Common Name: Dental Unit with Chair
Classification Name: Unit, Operative Dental
Device Class: I
Product Code: EIA
Regulation Number: 872.6640
Review Panel: Dental
Intended Use:

The Dental Unit with Chair is intended to supply power to and serve as a base for dental devices and accessories. It is intended for use in the dental clinic/office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.

2. Submitter Information

Sponsor and Manufacturer:
North West Medical Instrument (Group) Co., Ltd
No.3 Biyuan Road, Xianyang, 712000
Shaanxi, China

Contact Person of the Submission:
Ms. Diana Hong
Mr. Eric Chen
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, Zhongxin Zhongshan Mansion,
No.19, Lane 999, Zhong Shan Nan Er Road, 200230
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3. Predicate Device

K Number: K032543
C8+DENTAL OPERATIVE UNIT
Classification Name: Unit, Operative Dental
Product Code: EIA
Manufacturer: SIRONA DENTAL SYSTEMS GMBH.

4. Device Description

The applicant device of Dental Unit with Chair contains 6 types: S2300, S2305, S2308, S2315, S2318 and S2320. All of these types follow the same design principle and intended use, and comply with ISO7494-1, ISO7494-2 and ISO6875. The connection of these types complies with ISO9168.

All of these types of applicant device consist of similar components with similar function and different appearance, these components include: main box, connection box, assistant holder, foot control, telescopic tray arm, instrument tray, operating light.

5. Effectiveness and Safety Considerations

Effectiveness:

The Dental Unit with Chair comply with ISO7494-1, ISO7494-2, ISO6875 and ISO9168.

Safety Considerations:

The Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices". The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility.

The applicant device is compliance with IEC60601-1, Medical electrical equipment - Part 1: General requirements for safety and IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for safety -Collateral standard: Electromagnetic compatibility -. Requirements and tests

The Software Validation is in compliance with FDA Guidance to Compliance with FDA Guidance for the Content of PreMarket Submissions for Software Contained in Medical Devices.

6. Substantially Equivalence Determination

Comparison Analysis

The applicant device has same classification information, same indications and intended use, similar product design, similar technical specification, biological specification and safety specification. The applicant device doesn't provide the video system, but it is substantially equivalent to the predicate device in other parts.

Conclusion:

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

North West Medical Instrument (Group) Company, Limited
C/O Ms. Laura Danielson
Responsible Third Party Official
TUV SUD America, Incorporated
1775 Old Highway 8NW
New Brighton, Minnesota 55112

APR - 4 2008

Re: K080438
Trade/Device Name: Dental Unit with Chair
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: March 20, 2008
Received: March 21, 2008

Dear Ms. Danielson:

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.

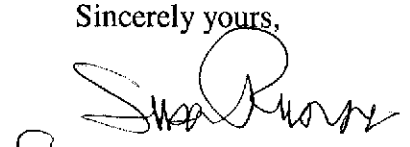
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Y.Indications for Use

510(k) Number: K082438

Device Name: Dental Unit with Chair

Indications for Use:

The Dental Unit with Chair is intended to supply power to and serve as a base for dental devices and accessories. It is intended for use in the dental clinic/office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.

Prescription Use ___√___ (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)

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

510(k) Number: K082438