Exhibit #9 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K130410

1. Date of Submission: January 25, 2013

JUL 26 2013

2. Sponsor

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

Establishment Registration Number: 3007031016

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3. Submission Correspondent
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Mid-Link Consulting Co., Ltd
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4. Proposed Device Identification

Proposed Device Name: Dental Unit with Chair
Proposed Device Model: S2310
Device Common Name: operative dental unit

Classification: I
Product Code: EIA
Regulation Number: 21 CFR 872.6640
Review Panel: Dental

Intended Use Statement:

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.

5. Predicate Device Identification

510(k) Number: K080438
Product Name: Dental Unit with Chair
Manufacturer: North West Medical Instrument (Group) Co., Ltd

6. Device Description

The proposed device Dental Unit with Chair S2310 is a well equipped with two hands operation dental unit, which 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.

The proposed device is modification device to Dental Unit with Chair S2318 (K080438). It and the existed device share the same intended use, similar configuration, function, safety and performance.

The proposed device consists of connection box, assistant holder, foot control, telescopic tray arm, instrument tray and operating light.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
IEC 60601-1-2: 2007, Medical Electrical Equipment -Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility -Requirements and Tests.
ISO7494-1: 2004, Dentistry - Dental units - Part 1: General requirements and test methods.
ISO7494-2: 2003, Dentistry - Dental units - Part 2: Water and air supply.
ISO 6875: 1995, Dental patient chair.
ANSI/AAMI/ISO17665-1: 2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

After performing non-clinical performance studies, the data shows that the proposed device

Substantially Equivalent (SE) to the predicate device.

8. Substantially Equivalent Comparison and Conclusion

Table III-1 Substantially Equivalent Comparison

ITEM		Proposed Device Dental Unit with Chair S2310	Predicate Device Dental Unit with Chair S2318 (K080438)
Product Code		EIA	EIA
Regulation No.		21 CFR 872.6640	21 CFR 872.6640
Class		I	I
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.	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.
Power Supply		110V	110V
Frequency		50/60Hz	50/60Hz
Power (with dental chair)		400VA	600VA
Operating Light	Power Supply	AC12V / 5W	AC 12V / 50W
	Illumination	≤20000lx	Weak: ≥8000lx Intense: ≥15000lx
Pressure of Water Supply		0.2MPa-0.4MPa	0.2MPa-0.4MPa
Air Supply Pressure		0.6MPa-0.8MPa	0.6MPa-0.8MPa
Dental Chair	Loading Capacity	200kg	135kg
	Movement Range (Chair)	390mm-740mm	410mm-750mm
	Movement Range (Backrest)	1°-70°	0°-70°
	Movement Range (Headrest)	150mm	150mm
Accessories can be attached to the device		High Speed Handpiece / Fiber Optic Handpiece/ Low Speed Handpiece / Scaler / Curing Light / Dental Chair / Three-way-Syringe	High Speed Handpiece / Fiber Optic Handpiece/ Low Speed Handpiece / Scaler / Curing Light / Dental Chair / Three-way-Syringe
Operation Method		Control Panel / Assistant Control Panel / Foot Controller	Control Panel / Assistant Control Panel / Foot Controller

Difference in Power (with dental chair), Illumination, and Dental Chair between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, Dental Unit with Chair S2310, is determined to be Substantially Equivalent (SE) to the predicate device, Dental Unit with Chair (K080438), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

Xianyang North West Medical Instrument (Group) Company, Limited
C/O Ms. Diana Hong
Mid-Link Consulting Company, Limited
P.O. Box 237-023
Shanghai, China 200237

Re: K130410
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: June 25, 2013
Received: June 28, 2013

Dear Ms. Hong:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II Indications for Use

510(k) Number: K130410
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)

☐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)

Susan Runner DDS, MA Mary S. Runner -S 2013.07.26 10:50:57 -04'00'

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

510(k) Number: K130410