K103550

510(K) SUMMARY

JAN - 4 2011

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92

1.0 Submitter's Information

Establishment Registration Name:

Foshan Yoboshi Medical Equipment Co., Ltd.

4 Simple Workshop, East city road, （Fuwan） hecheng city street,
Gaoming, Foshan, Guangdong
China 528500

Contact Person of applicant
Mr. Jianjun Zhong – Management Representative
4 Simple Workshop, East city road, （Fuwan） hecheng city street,
Gaoming, Foshan, Guangdong
China 528500

TEL: +86-757-2885 3333
FAX: +86-757-2890 1866
Email:

Contact Person of the Submission:

Ms. Sabrina Wei

MEDLAB (Shenzhen) Information Service Co., LTD

Room 2706, Block A, ZhongFang JinYuan Buiding, Xinwen Road
Shenzhen, Guangdong, P.R. China, 518034

TEL: +86-755-83089699
FAX: +86-755-83089760
Email: sabrinawei@hotmail.com ; please CC lingbensuo@gmail.com,

2.0 Device Information

Type of 510(k) submission:	Traditional
Device Common Name:	Dental Unit with Chair
Trade Name:	Yoboshi Dental Unit
Model:	A8000, A8000-I, A8000-II
Classification name:	Dental operative unit and accessories

Review Panel:	Dental
Product Code:	EIA
Regulation Class:	I
Regulation Number:	872.6640

3.0 Predicate Device Information

Sponsor:	North West Medical Instrument (Group) Co., Ltd
Device:	Dental Unit with Chair, Model: S2300
510(K) Number:	K080438

4.0 Device description

Yoboshi dental units with chairs are driven by imported low-voltage DC motor with imported air spring auxiliary balance to keep a safe and stable operation of equipment and low noise. With two pieces of NSK high speed H.P and one piece of NSK low-speed H.P, it is easy and credible for working. The single-form seamless leather cushion provides comfort for the patient to sit and lie and for the doctor to clean and disinfect more easily. It is applicable for the dentist and dental clinic. The unit is composed of integral ceramic spittoon, air-controlled balanced instrument-arm, newly-designed cold light.

The models include A8000, A8000-I, A8000-II. All of these types follow the same design principle and intended use, and comply with ISO7494-1:2004, ISO7494-2:2003. The hose connectors of these types comply with ISO9168:1991. The air-motors of these types comply with ISO13294: 1997. Dental patient chair complies with ISO 6875:1995.

All of these types of applicant devices consist of similar components with similar function and different appearance, these components include:

- Electric pedal switch
- Control key for mouth lamp
- Wash cuspidor
- Gargle water control
- Pedal switch
- Handrail
- Backrest
- Headrest
- Cuspidor
- Rising pipe
- Lamp arm
- Operation light
- Seat cushion for child

5.0 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

6.0 Effectiveness and Safety Considerations

Effectiveness:
The Dental Unit with Chair complies with ISO7494-1:2004, ISO7494-2:2003, ISO9168: 1991, ISO 6875:1995 and ISO13294: 1997.

Safety Considerations:

The applicant devices comply 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.

For all hose connectors and air motors, the applicant devices comply with ISO 9168: 1991 and ISO 13294: 1997.

For dental patient chair, the applicant devices comply with ISO 6875:1995.

In regard to biocompatibility evaluation, the applicant devices comply with ISO 111381-1: 2006 for BI material, ISO 11737-1: 2006 for disposable anesthesia channel; ISO 10993-5 & -10 for Single-use anesthesia tube.

The Software Validation is in compliance with FDA Guidance for the Content of Pre-Market Submissions for Software Contained in Medical Devices.

7.0 Comparison to predicate device and conclusion

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 video system of the applicant device is optional for Model A8000 & A8000-I, and 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 marketed device. Therefore, the applicant device is determined as safe and effectiveness.

Compare with predicate device, they are very similar in design principle, intended use, functions, material and the adopting applicable standards. The differences between applicant device and predicate device do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Fosham Yoboshi Medical Equipment Company, Limited
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

JAN - 4 2011

Re: K103550
Trade/Device Name: Yoboshi Dental Unit with Chair
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: December 21, 2010
Received: December 22, 2010

Dear Mr. Job:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K103550

JAN - 4 2011

Device Name: Yoboshi Dental Unit with Chair

Model: A8000, A8000-I, A8000-II

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)

Susan Finger

Division Sign-Off)
ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K103550

Concurrence of CDRH, Office of Device Evaluation (ODE)