K093971

APR 22 2010

Chapter III 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. **Device Information**
   Device Common Name: Handpiece, Air Powered, Dental
   Device Trade/Proprietary Name:
   a. **High Speed Air Turbine Handpiece series**
   b. **Dental Low Speed Handpiece including Air Motor Straight and Geared Angle Handpiece series**

   Classification Information:
   a. **High Speed Air Turbine Handpiece series**
   1. **Classification Name:** Handpiece, Air Powered, Dental
   2. **Regulation Number:**872.4200
   3. **Product Code:** EFB
   4. **Class:** I
   5. **Review Panel:** Dental

   b. **Dental Low Speed Handpiece including Air Motor Straight and Geared Angle Handpiece series**
   (1) **Classification Name:** Handpiece, Air Powered, Dental
   (2) **Regulation Number:**872.4200
   (3) **Product Code: EFB**
   (4) **Class:** I
   (5) **Review Panel:** Dental

2. **Submitter Information**

   Manufacturer Name and Address

   North West Medical Instrument (Group) Co., Ltd

   No.3 Biyuan Road, Xianyang,
   Shaanxi 712000, P. R.China

Contact Person of the Submission
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3. Device Description

3.1 High Speed Air Turbine Handpiece series

There are two series (total 12 models) handpieces in this high speed hanhpiece series as A and B series. A series means the initial of model is "A", which include Quick Coupling, B series means the initial of model is "B", which doesn't include Quick Coupling.

The High Speed Air Turbine Handpiece series device is reusable device, but they should be sterilized before use, the sterilization method please refer to Section 1.4 of Chapter VIII information manual.

In the A series of High Speed Air Turbine Handpiece series device, there are 2 models (AZL-4 and ADZ-4) device have one especial different from other model. These two model device have illumination function implemented via LED, the power supply of which is 3.3V d.c. and supplied by Therapy Machine.

All the variant types of High Speed Air Turbine Handpiece series follow the same principle with the same intended use and are made of same materials

The applicant device is not for life-supporting or life-sustaining, not for implant. The device is for prescription. The device does not contain drug or biological product. The device are not provided as sterile, they can be reusable and re-sterilized by the user. The device is not software-driven device.

3.2 Dental Low Speed Handpiece including Air Motor Straight and Geared Angle Handpiece series

This series devices is the low speed handpiece device which includes 2 air motors (model 0222 is two hole motor; model 0224 is four hole motor), one

straight head (model 043) and one contra angle head (model 058E). the two air motor can be matched with the straight or contra angle head discretional for different condition.

The Dental Low Speed Handpiece including Air Motor Straight and Geared Angle Handpiece series device is reusable device, but they should be sterilized before use, the sterilization method please refer to Section 2.4 of Chapter VIII information manual.

All the variant types of Dental Low Speed Handpiece including Air Motor Straight and Geared Angle Handpiece series follow the same principle with the same intended use and are made of same materials

The applicant device is not for life-supporting or life-sustaining, not for implant. The device is for prescription. The device does not contain drug or biological product. The device are not provided as sterile, they can be reusable and re-sterilized by the user. The device is not software-driven device.

4. Intended Use

High Speed Air Turbine Handpiece series

This device is an air-powered hand-held device, intended to prepare dental cavities for restorations, such as tooth body treatment, tooth drilling and tooth grinding of stomatology.

Dental Low Speed Handpiece including Air Motor Straight and Geared Angle Handpiece Series

This device is an air-powered hand-held device, intended for removing curious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations, restorations and polishing teeth for use by a trained professional in general dentistry.

5. Substantially Equivalence Determination

Predicate Device

a. INTEGRITY Low Speed Den Hi-Speed Turbine Handpiece
K-number: K070155
Manufactured by: Osseo Scientific, LLC

b. **Hi-Speed Turbine Handpiece**
K-number: K071561
Manufactured by: Beijing North Pole Dental Handpiece Co., Ltd.

The applicant devices are substantially equivalent to claimed predicate devices with respect to safety and effectiveness.

6. Test Summary

6.1 High Speed Air Turbine Handpiece series

The performance of device following ISO7785-1:1997 and ISO9168:1991 were conducted.

For the model AZL-4 and ADZ-4, because of the illumination set, these two models device are electrically operated and the electrical safety and electromagnetic compatibility following IEC 60601-1 and IEC60601-1-2 were conducted.

6.2 Dental Low Speed Handpiece including Air Motor Straight and Geared Angle Handpiece series

The performance of device following ISO7785-2:1995, ISO13294:1997and ISO9168:1991 were conducted.

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

North West Medical Instrument (Group) Company, Limited
C/O Ms. Dawn Tibodeau
Responsible Third Party Official
TÜV SÜD America, Incorporated
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

APR 22 2010

Re: K093971
Trade/Device Name: High Speed Air Turbine Handpiece Series and Dental Low Speed Handpiece Including Air Motor Straight and Geared Angle Handpiece Series
Regulation Number: 21CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: April 12, 2010
Received: April 14, 2010

Dear Ms. Tibodeau:

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 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

K093971

Premarket Notification 510(k) Chapter II Indication for Use Statement
Report No.:

Indication For Use

510(k) Number (if known): Pending

Device Name: High Speed Air Turbine Handpiece series

Indications for Use:

This device is an air-powered hand-held device, intended to prepare dental cavities for restorations, such as tooth body treatment, tooth drilling and tooth grinding of stomatology.

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)

Kevi Mulay for MSR

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

510(k) Number: K093971

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Premarket Notification 510(k) Chapter II Indication for Use Statement
Report No.:

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510(k) Number (if known): Pending

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This device is an air-powered hand-held device, intended for removing curious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations, restorations and polishing teeth for use by a trained professional in general dentistry

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)

Kevin Mulloy for MSR

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

510(k) Number: K093971