January 13, 2020

Dentsply Sirona
Karl Nittinger
Vice President, Corporate Regulatory Affairs
221 W Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K192409
Trade/Device Name: Midwest Rhino XE and Air Motor M
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: October 14, 2019
Received: October 15, 2019

Dear Karl Nittinger:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192409

Device Name
Midwest Rhino XE and Air Motor M

Indications for Use *(Describe)*
Low-speed (vane motor) handpiece is used for drilling of teeth in a variety of dental procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5. 510(k) SUMMARY
for
Midwest Rhino XE and Air Motor M
(K192409)

Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
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Email: karl.nittinger@dentsplysirona.com

Date Prepared: January 13, 2020

Device Name:

- Proprietary Name: Midwest Rhino XE and Air Motor M
- Common Name: Handpiece, Air-Powered, Dental
- Classification Name: Dental Handpiece and Accessories
- CFR Number: 872.4200
- Device Class: I
- Product Code: EFB

Predicate Device:

Predicate Device Name	510(k)	Company Name
LS-100	K792302	Dentsply Sirona

Reference Device Name	510(k)	Company Name
W&H Air-Powered Handpieces and Handpiece Attachments (Air Motor AM-25-E RM)	K162926	W&H Dentalwerk GmbH

Description of Device:

The Midwest Rhino XE and Air Motor M are low speed air motors. The motors are reusable and can be sterilized in an autoclave. Air Motor M includes an external spray port whereas the Midwest Rhino XE does not have the external spray port.

Indications for Use:

Low-speed (vane motor) handpiece is used for drilling of teeth in a variety of dental procedures.

Substantial Equivalence:

The subject devices have identical indications for use as the predicate device, LS-100 (K792302). Table 5.1 show a comparison of the indications for use and technological features of the proposed devices and the predicate device.

Table 5.1- Comparison of proposed devices and the predicate device

Element	Proposed Devices		Predicate Device	Reference Device	Differences
	Midwest Rhino XE	**Air Motor M**	**LS-100 (K792302)**	**W&H Air-Powered Handpieces and Handpiece Attachments (Air Motor AM-25 E RM) (K162926)**	
Indications for Use	Low-speed (vane motor) handpiece is used for drilling of teeth in a variety of dental procedures.		Low-speed (vane motor) handpiece is used for drilling of teeth in a variety of dental procedures.	The turbine handpiece is intended for the following applications: removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces. The dental handpiece/contra-angle is intended for the following applications: removal of decayed materials, cavities and crown cement, removal of fillings, finishing and polishing of tooth and restorations surfaces.	Identical for the predicate device as used in a variety of dental activities. Similar to the reference device indications for use for which are detailed as to the specific application the device is used.
Operational Mode	Air-powered		Air-powered	Air-powered	Identical
Operating Pressure (psi)	42 ± 2.9		40-45	42	There is no significant difference in the operating pressure of the proposed air motors when comparing them to the predicate air motor. The proposed devices fall within the cleared range of the predicate device.
Motor Speed (rpm)	0 - 24,000	≥18,000	0-8,000	2.2 bar: 5,000-20,000* 3 bar: 5,000-25,000*	The difference of the motor speed comes through the planetary gearing of the proposed Midwest Rhino XE and Air Motor M. Conformity testing to the requirements of ISO 14457 requirements are included to support substantial equivalence.

Table 5.1- Comparison of proposed devices and the predicate device					
Element	**Proposed Devices**		**Predicate Device**	**Reference Device**	**Differences**
	Midwest Rhino XE	**Air Motor M**	**LS-100 (K792302)**	**W&H Air-Powered Handpieces and Handpiece Attachments (Air Motor AM-25 E RM) (K162926)**	
Torque (N/cm)	~2.0	~2.1	~6	4	The difference of the motor torque comes through the planetary gearing of the Midwest Rhino XE and Air Motor M. It changes speed into torque. Conformity testing to the requirements of ISO 14457 requirements are included to support substantial equivalence.
External Spray Port	NA	Yes	NA	Yes	The external spray port in the design of the proposed Air Motor M is an optional feature to facilitate connection of dental instruments with an external spray connection.
Spray Air Pressure in bar (psi)	NA	2.3 ± 0.2 33.4 ± 2.9	NA	2.2-3*	
Spray Water Pressure in bar (psi)	NA	2.0 ± 0.2 29.0 ± 2.9	NA	1.5-2.5*	
Sterilization	Steam Autoclave		Steam Autoclave	Steam Autoclave	Identical
Lubricant	Sirona T1 Spray (K150750)	Sirona T1 Spray (K150750)	Sirona T1 Spray (K150750)	W&H Service Oil F1, MD-400	Identical
Type of Chuck	ISO-Coupler	ISO-Coupler	Midwest-Coupler	ISO 3964 connection	The proposed devices are identical to the predicate device.
Coupling	Midwest 4-hole coupling	Midwest 4-hole coupling Borden 2/3-hole coupling	Midwest 4-hole coupling	Fixed connection standard 4-hole*	The Air Motor M is also available in version with a Borden 2/3-hole coupling. This coupling is another type of connection that can be used to connect the handpiece to the air motor hose.

Non-Clinical Performance Data.

Testing to verify the performance requirements of the proposed devices, Midwest Rhino XE and Air Motor M, was conducted and included in this premarket notification. The results of the performance testing support substantial equivalence.

Tests included in this premarket notification verify the conformity of the proposed devices, Midwest Rhino XE and Air Motor M, with the requirements of:

- EN ISO 17665-1- Sterilization of health care products-Moist heat Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ANSI/AAMI ST79:2010 and A1:2010 and A2:2011 and A3:2012 and A4:2013- Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Reprocessing validation per the FDA Guidance Document entitled, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" dated March 17, 2015
- Cleaning Process Validation per AAMI TIR 30 and ISO 15883-5
- ISO 14457:2-17-10- Dentistry-Handpiece and motors
- ISO 9168-Dental Handpieces-Hose Connections
- ISO 3964-Dental Handpiece-Coupling dimensions
- Biocompatibility equivalency with the reference device (K150750) as far as material composition is included in support of substantial equivalence. The equivalency statement is made in reference to the requirements of ISO 10993-1:2010-*Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and ISO 7405:2013-*Dentistry-Evaluation of biocompatibility ofmedical devices used in dentistry*.
- ISO 13504:2012-Dentistry-General requirements for instruments and related accessories used in dental implant placement and treatment
- Guidance for Industry and FDA Staff-Dental Handpieces-Premarket Notification [510(k)] Submissions

Risk Analysis

Risk analysis was performed on the proposed devices based on ISO 14971. The results of the risk analysis performed concluded that all device design controls and process controls will be able to mitigate known potential failures andeffect.

Clinical Performance Data.

No data from human clinical studies has been included to support the substantial equivalence of the proposed Midwest Rhino XE and Air Motor M handpieces.

Conclusion Regarding Substantial Equivalence

The proposed Midwest Rhino XE and Air Motor M handpieces are air-powered dental handpieces which are used for drilling of teeth in a variety of dental procedures. The proposed Midwest Rhino XE and Air Motor M handpieces have identical indications for use as those cleared for the predicate device, LS-100 (K792302). The proposed devices incorporate the same fundamental technology and have same intended uses as the predicate device, LS-100 (K792302) and the reference device, W&H Air-Powered Handpieces and Handpiece Attachments (Air Motor AM-25 E RM) (K162926). Test data according to ISO 14457:2017-10 to verify the performance of the Midwest Rhino XE and Air Motor M handpieces has been provided and the results of this testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence.