DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 11, 2017

Nakanishi, Inc.
% Izumi Maruo
Senior Consultant
MIC International Corp.
4-1-17 Hongo
Bunkyo-ku, Tokyo 1130033
JAPAN

Re: K163131
Trade/Device Name: A-dec NLZ Electric Motor System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EBW
Dated: April 24, 2017
Received: April 25, 2017

Dear Izumi Maruo:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163131

Device Name
A-dec NLZ electric motor system

Indications for Use *(Describe)*
The A-dec NLZ electric motor system is comprised of a control unit that drives a direct current (DC) electric micromotor that is activated by means of a foot control. It is intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment, with use of a straight, right-angle or contra-angle ISO E-type handpiece attachment of equal, gear-reducing, or gear-increasing speed.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

a. Owner/Company name, address

NAKANISHI INC.
700 Shimohinata, Kanuma-shi,
Tochigi, 322-8666, Japan

b. Contact

Kimihiko Satoh
General Manager, Regulatory Affairs Department
NAKANISHI INC.
700 Shimohinata, Kanuma-shi,
Tochigi, 322-8666, Japan

Phone: +81-289-64-4325
Fax: +81-289-62-6665
Email: k-satoh@nsk-nakanishi.co.jp

c. Application Correspondent

Izumi Maruo
Senior Consultant
MIC International
4-1-17 Hongo, Bunkyo-ku
Tokyo, 113-0033, Japan

Phone: +81-3-3818-8577
Fax: +81-3-3818-8573
Email: maruo@mici.co.jp

d. Date prepared

May 10, 2017

e. Name of device

Trade Name:	A-dec NLZ Electric Motor System
Classification Name:	Controller, Foot, Handpiece and Cord
Regulation Name:	Dental handpiece and accessories
Regulatory Class:	Class I
Product Code:	EBW

f. Predicate devices

The A-dec NLZ electric motor system is substantially equivalent to the following legally marketed device:

510(k):	K133776
Trade name:	A-dec/W&H Electric Motor, Model EA-53
Product code:	EBW

g. Description of the device

The A-dec NLZ electric motor system is intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment, with use of a straight, right-angle or contra-angle ISO E-type handpiece attachment of equal, gear-reducing, or gear-increasing speed.

Control Unit, Motor and Motor Tubing are constituents of the A-dec NLZ electric motor system under this 510(k) application. The A-dec NLZ electric motor system is intended for use only with the A-dec 300 (K082985) or A-dec 500 (K032756) delivery system. The A-dec 300 (K082985) or A-dec 500 (K032756) delivery system offers operation modes for use with the A-dec NLZ electric motor system.

The Control Unit of the A-dec NLZ electric motor system is contained within the control head of the A-dec 300 (K082985) or A-dec 500 (K032756). The subject device acquires +24 VAC electrical power from the delivery system to the Control Unit. User can control the motor system through Touch Pad and Foot Controller of the delivery system. The control unit receives instructions such as motor rotation/stop, speed setting value, torque setting value, and LED turning ON/OFF from Touch Pad and Foot Controller. The Control Unit drives the Motor using instructed rotation speed and torque via Motor Tubing. The delivery system provides standard mode (range of rotation speed is 1,000 - 40,000 rpm) and endo mode (range of rotation speed is 100 – 5,000 rpm).

The Motor Tubing is connected to the Control Unit via a lead wire and air/water supply via tubing inside the control head of the delivery system. The other side of the Motor Tubing is attached to the Motor.

h. Indications for Use

The A-dec NLZ electric motor system is comprised of a control unit that drives a direct current (DC) electric micromotor that is activated by means of a foot control. It is intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment, with use of a straight, right-angle or contra-angle ISO E-type handpiece attachment of equal, gear-reducing, or gear-increasing speed.

i. Statement of substantial equivalence

The Indications for Use of the A-dec NLZ electric motor system is similar to the predicate. Other features of the subject device are similar to the predicate.

Following table is comparison between the A-dec NLZ electric motor system and the predicate.

Table 1. Comparison table between the A-dec NLZ electric motor system and the predicate

	A-dec NLZ electric motor system	A-dec/W&H Electric Motor, Model EA-53 (K133776)
Indications for Use	The A-dec NLZ electric motor system is comprised of a control unit that drives a direct current (DC) electric micromotor that is activated by means of a foot control. It is intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment, with use of a straight, right-angle or contra-angle ISO E-type handpiece attachment of equal, gear-reducing, or gear-increasing speed.	The A-dec/W&H Electric Motor kit is a device system comprised of a control unit that drives a DC electric micromotor that is activated by means of a footswitch. It is intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis, and endodontic treatment, with use of a straight, right- angle, or contra-angle ISO E-type handpiece attachment of equal speed, gear-reduction speed, or gear-increasing speed.
Drive	Electronic-micromotor	Electronic-micromotor
Components	Motor controller, Electric micromotor, Motor tubing	Motor controller, Electric micromotor, Motor tubing
Size		
-Motor controller	D78.5 x W148.0 x H43.0 (Protruding parts not included.)	D60 x W120 x H44 (Protruding parts not included.)

-Motor	Length : 31 mm Diameter : Φ20.1(Front) Φ22.1(Rear)	Length : 31 mm Diameter : Φ20.7(Front) Φ21.3(Rear)
-Motor tubing	Length of tubing NLZ CDAS: 1600 mm NLZ CDAL: 2080 mm	Length of tubing 2080 mm
Material of Motor exterior	Titanium	Stainless steel
Light	LED	LED
Range of rotation speed (rpm) (standard mode)	1,000 - 40,000 rpm	1,000 - 40,000 rpm
Range of rotation speed (rpm) (endo mode)	100 – 5,000 rpm	100 – 5,000 rpm
Rotating direction	Forward and Reverse	Forward and Reverse
Torque		
- Standard Mode Maximum Torque (Stall Torque)	4.00 Ncm (Measured value)	4.10 Ncm (Measured value)
- Endo Mode Torque Range	0.30 - 3.00 Ncm	0.30 - 3.00 Ncm
Coolant mechanism	Coolant air	Coolant air
Sterilization	Sterilized by user (steam sterilization)	Sterilized by user (steam sterilization)
Available Handpiece type	E-type (ISO3964)	E-type (ISO3964)
Usage environment	Temperature : 0 - 40ºC Humidity : 30 – 75% RH	Temperature : 10 - 33 ºC

In the comparison table, there are some differences in characteristics between the A-dec NLZ electric motor system and the predicate. We considered that the differences did not affect the identical principles of operation between the A-dec NLZ electric motor system and the predicate. Performance testing including biocompatibility testing, Electric safety and EMC testing, bench testing was performed in order to demonstrate substantial equivalence to the predicate. Also, sterilization validation and software validation were performed in accordance with FDA guidance. The A-dec NLZ electric motor system met all requirements of the standards. Therefore, the A-dec NLZ electric motor system demonstrated substantial equivalence to the predicate.

j. Biocompatibility

Following biocompatibility test was performed:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10: 2010)

- Irritation (ISO 10993-10: 2010)

In the biocompatibility testing reports, no biocompatibility concern was raised.

k. Bench Testing

The bench tests were performed in order to verify conformity to ISO 14457.

All A-dec NLZ electric motor system samples were compliant with ISO 14457.

Also, electromagnetic compatibility testing in accordance with IEC 60601-1-2 and electrical safety testing in accordance with IEC 60601-1 were performed. Those test results indicate that the A-dec NLZ electric motor system does not raise concern.

Software validation was conducted in accordance with FDA guidance entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005" and sterilization validation of the Motor was conducted in accordance with FDA guidance entitled "Reprocessing Medical Devices in Health Care Settings: Validation Method and Labeling Guidance for Industry and Food and Drug Administration Staff". In addition, infection/cross-contamination risk analysis of the Motor tubing in accordance with ISO14971 was conducted. Based on the risk analysis, verification testing was performed in order to evaluate the possible introduction of biological materials (e.g. blood, bone, saliva) into the Motor tubing due to backflow. No backflow into the Motor and Motor tubing was detected in the verification testing.

In order to evaluate extractables/leachables of the water circuit of the subject device, the elution testing was performed. The extractables/leachables were not detected.

No animal or clinical testing was performed.

l. Conclusion

The indications for use of the A-dec NLZ electric motor system is similar to the predicate. Although there are some differences in characteristics between the A-dec NLZ electric motor system and the predicate, a number of performance testing indicated that the A-dec NLZ electric motor system met the requirement of the standards. Based on above results, we conclude the A-dec NLZ electric motor system is substantially equivalent to the predicate.