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

August 31, 2017

Nakanishi Inc.
% Izumi Maruo
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JAPAN

Re: K163402
Trade/Device Name: NLZ Motor System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EBW
Dated: July 21, 2017
Received: August 1, 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,

Andrew I. Steen -S

for Lori A. Wiggins, MPT, CLT
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)*
K163402

Device Name
NLZ Motor System

Indications for Use *(Describe)*
The NLZ Motor System is intended for use by dental professionals in the performance of dental restoration, prophylaxis and endodontic procedures.

The NLZ Endo is intended for use by dental professionals in the performance of dental endodontic 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)

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)*

K163402

510(k) Summary

a. Owner/Company name, address

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d. Date prepared

July 21, 2017

e. Name of device

Trade Name:	NLZ 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 and reference device

Predicate device

510(k):	K090937
Trade name:	E-STATIS 40 Electric Motor System
Company name:	SciCAN
Product code:	EBW

The E-STATIS 40 Electric Motor System (K090937) does not include a handpiece. Therefore, the predicate device for the contra-angle handpiece, NLZ Endo is shown below.

Predicate device for the NLZ Endo

510(k):	K150750
Trade name:	Contra-Angle Handpiece :Endo 6:1
Company name:	Sirona Dental Systems GmbH
Product code:	EGS

This submission uses following reference device for the reciprocating mode of the NLZ Motor System. The E-STATIS 40 Electric Motor System (K090937) is not equipped with that mode.

Reference Device

510(k):	K103653
Trade name:	e3^{TM} Torque Control Motor
Company name:	DENTSPLY International Inc.
Product code:	EBW

510(k):	K103027
Trade name:	ELECTROtorque TLC 4893 with INTRAmatic KL 702
Company name:	Kaltenbach & Voigt GmbH
Product code:	EBW, EKX

g. Description of the device

NLZ Motor Systems are available in two models;
NLZ Motor Set, which consists of the Main Unit, the Control Unit and the Motor.
NLZ E Motor Set, which consists of the Main Unit, the Control Unit, the Motor, and the Contra Angle Handpiece: NLZ Endo. The NLZ Endo is available only for NLZ E Motor Set and is not avialable for the NLZ Motor Set. The NLZ Endo is not equipped with any cooling system because it is a speed-reducing/low-speed handpiece.

The Control Unit drives an electric micromotor, and turns on or off or regulates the speed of an electric motor by its foot pedal of the dental unit. This product can be connected to dental

units currently in use to add on a brushless electric micromotor with an LED light.

h. Indications for Use

The NLZ Motor System is intended for use by dental professionals in the performance of dental restoration, prophylaxis and endodontic procedures.

The NLZ Endo is intended for use by dental professionals in the performance of dental endodontic procedures.

i. Statement of substantial equivalence

The Indications for Use of the NLZ Motor System is identical to the E-STATIS 40 Electric Motor System (K090937).

The NLZ Motor System and the E-STATIS 40 Electric Motor System (K090937) have the similar functions and characteristics regarding the range of rotating speed, rotation direction, and auto reverse/auto stop.

The NLZ Motor System is equipped with similar reciprocating mode to the reference device.

Following table is comparison between the subject, the predicate and the reference devices.

Table 1. Comparison table for outline of the motor system

	Subject Device	Predicate Device	Reference Device	Reference Device
	NLZ Motor System	E-STATIS 40 Electric Motor System (K090937)	ELECTROtorque TLC 4893 (K103027)	e3™ Torque Control Motor (K103653)
Indications for Use	The NLZ Motor System is intended for use by dental professionals in the performance of dental restoration, prophylaxis and endodontic procedures. [Indications for Use for NLZ Endo] The NLZ Endo is intended for use by dental professionals in the performance of endodontic procedures.	The E-STATIS type 40 dental system is intended for use by dental professionals in the performance of dental restoration, prophylaxis and endodontic procedures.	*The ELECTROtorgue **T**LC 4893* is intended to convert pneumatic output from a dental treatment center to electrical energy to drive the *INTRAmatic KL **702*** motor for operation of electrically driven dental handpieces. These devices are designed for use by a trained professional in the field of general dentistry.	The e3 Torque Control Motor is a medical device designed for use by dentists for use with dental root canal instruments in continuous rotation with torque control or in reciprocating movement.
Drive	Electronic-micromotor	Electronic-micromotor	Electronic-micromotor	Electronic-micromotor
Components	Power supply, Motor controller, Electric micromotor, and Contra-angle handpiece (NLZ Endo, NLZ E Motor Set ONLY)	Power supply, Motor controller, and Electric micromotor	Power supply, Motor controller, and Electric micromotor	Power supply, Motor controller, Foot pedal, Electric micromotor and Contra-angle handpiece (K972436)
Light	LED	Light bulb	LED	No light
- Light intensity	>10,000[Lx]	Unknown	Unknown	NA

Range of rotation speed (rpm)	100 - 40,000 rpm	100 - 40,000 rpm	100 - 40,000 rpm	250 – 1,000 rpm
Rotating direction	Forward and Reverse	Forward and Reverse	Forward and Reverse	Forward and Reverse
Standard operation mode	Yes	Yes	Yes	No
-Overheating risk reduction features	Yes*	No	Yes*	NA
Reciprocating mode	Yes (NLZ E Motor Set ONLY)	No	No	Yes
-Intended file	WaveOne	NA	NA	Wave One
-6:1 gear ratio handpiece designed for rotary and reciprocating modes is provided with the Motor	Yes	NA	NA	Yes
- Preset parameters for the reciprocating mode	Yes (User cannot alter the parameters)	NA	NA	Yes (User cannot alter the parameters)
Rotary Endo Mode	Yes (NLZ E Motor Set ONLY)	Yes	Yes	Yes
- Auto reverse/Auto Stop function	Yes	Yes	Yes	Yes

Motor overheating prevention function	Yes	Unknown	Yes	Unknown
Maximum air/water pressure				
-Coolant air supply	0.40 MPa	0.40 MPa	0.5 MPa	No coolant circuit
-Spray water supply	0.25 MPa	0.25 MPa	0.25 MPa	No spray circuit
-Spray air supply	0.25 MPa	0.20 MPa	0.20 MPa	No spray circuit
Sterilization	Sterilized by user (steam sterilization)	Sterilized by user (steam sterilization)	Sterilized by user (steam sterilization)	The contra-angle handpiece only is sterilized by user
Available Handpiece type	E-type (ISO3964)	E-type (ISO3964)	ISO3964 conformed attachment	E-type (ISO3964)

* For detail comparison regarding overheating risk reduction features, please see Table 2.

Based on Table 1, the NLZ E Motor Set provides “Reciprocating Endo Mode” and “Rotary Endo Mode” in addition to standard operation mode (in the NLZ Motor System, named “General Application Mode”). The Reciprocating Endo Mode of the NLZ E Motor Set is designed for use with WaveOne file designed for unequal counterclockwise (150°) and clockwise (30°) rotation. In order to perform reciprocating endo treatment safely, we provide the NLZ Endo handpiece which was verified for use with the WaveOne and presetting parameters of this treatment for the NLZ Endo with the WaveOne on the NLZ E Motor Set. User cannot alter those presetting parameters. The reciprocating mode of the reference device, e3^{TM} Torque Control Motor (K103653) has identical features to the Reciprocating Endo Mode, which means;

1. Both modes are designed for use with WaveOne file
2. Both modes provide automatic unequal counterclockwise (150°) and clockwise (30°) rotation
3. Both modes provide a 6:1 handpiece which was verified for use with the WaveOne and presetting parameters for using the providing handpiece combined with the WaveOne file.
4. User cannot alter the presetting parameters

The Rotary Endo Mode of the NLZ E Motor Set provides the continuous one direction rotation for use with low-speed handpieces and three modes when the set torque reached. The values of rotation speed and torque can be adjusted. The features for “Endodontic Mode” of the E-STATIS 40 Electric Motor System (K090937) are identical to those for this mode.

Regarding standard operation mode, the provided rotation direction and range of rotation speed of the subject device are identical to those of the E-STATIS 40 Electric Motor System (K090937). Although the NLZ Motor System is equipped with the overheating risk reduction functions in order to reduce patient burns caused by overheated handpiece, the predicate device E-STATIS 40 Electric Motor System (K090937) is not equipped with such function. Therefore, such functions of the subject device are compared with a reference device, ELECTROtorque TLC 4893 (K103027).

Table 2. Comparison of overheating risk reduction functions

Overheating risk reduction function	NLZ Motor System (K163402/S001)	ELECTROtorque TLC 4893 (K103027)
Detection of defective handpieces	Contra-SAFE	SAFEdrive
- Detection of overheating	Indirectly by measuring load for the handpiece and the duration of time	Indirectly by continuous monitoring of the idling properties of the handpiece during its use.
- Features	This function automatically stops motor rotation or controls the speed when higher and continued load of motor current are detected.	If the protective function is triggered, the SAFEdrive initially reduces the motor speed and then stops the motor altogether if the excessive load persists
Judge and display of the handpiece status	Contra-Check	The device does not have this function
- Features	1) A manual feature for indirect detection of excessive friction by measuring current consumption of the Motor 2) Providing the status of handpiece regarding potential overheating as follows; ● OK: The check result is acceptable ● OIL: Needs a maintenance such as lubricating with oil ● NG: There is a serious malfunction ● NG blinking: Damaged handpiece	NA
Motor speed control function after Contra-Check	Contra-Restriction	NA
-Features	This function restricts motor rotation when handpiece is used for judge other than OK through estimating temperature increase by the Control Unit. The motor is slowed down and stopped after speed control.	NA

	● If NG blinking is displayed, the motor is stopped and cannot be activated. ● If NG is displayed, the motor is stopped approximately 10 seconds after continuous use. ● If Oil is displayed, the motor is stopped approximately 20 seconds after continuous use.	

In addition, the subject device and the ELECTROtorque TLC 4893 (K103027) are equipped with the Motor overheat prevention function. The motor overheat prevention function indirectly detects overheat of the Motor itself in order to protect the Motor from failure of the coils. The purpose of design for this function is different from handpiece overheating risk reduction features described above.

This function of the subject device estimates temperature increase of the Motor by the motor current and rotation speed. The ELECTROtorque TLC 4893 (K103027) detects overload.

Regarding the handpiece, the comparison table is shown below;

Table 3. Comparison table for the Contra-angle handpiece

	NLZ Endo	Contra-Angle Handpiece :Endo 6:1 (K150750)
Design features	Contra-Angle, Push-Button Chuck, Motor coupling, Without light and cooling system	Contra-Angle, Push-Button Chuck, Motor coupling, Without light and cooling system
Gear ratio	6:1 Reduction	6:1 Reduction
Maximum motor/drive speed	6,000 rpm	40,000 rpm
Materials	Stainless Steel	Stainless Steel
Motor coupling	Compliant with ISO 3964	Compliant with ISO 3964
Source of power	Electronic-micromotor NLZ E Motor Set Only	Electronic-micromotor
Dimension	Head Diameter: 8.6mm Head Height: 11.3mm Length: 81.9mm	Head Diameter: 8.7mm Head Height: 11.4mm Length: 92.3mm
Weight	66 g	70 g
Performance	Compliant with ISO 14457	Compliant with ISO 14457
-Eccentricity	0.018 mm	Unknown
-Force for bur extraction	>45N	Unknown
Sterilization	Sterilized by user (steam sterilization)	Sterilized by user (steam sterilization)
Lubricant	PANA SPRAY Plus (510(k) number is K131014)	Sirona T1 spray (510(k)number is K113674)

Bur	Contra-angle burs ISO1797-1 Type1	Contra-angle burs ISO1797-1 Type1
-Maximum bur length	46 mm	25 mm

Both the NLZ Endo and the Contra-Angle Handpiece :Endo 6:1 (K150750) are used for dental endodontic procedures. The main design features and gear ratio of the NLZ Endo are similar to those of the Contra-Angle Handpiece :Endo 6:1 (K150750). Although there are some differences between the NLZ Endo and the Contra-Angle Handpiece :Endo 6:1 (K150750), the performance characteristics of both devices are compliant with ISO 14457.

For the NLZ Motor System, performance testing including biocompatibility testing, Electric safety and EMC testing, bench testing was performed in order to demonstrate substantial equivalence to the predicates. Also, reprocessing validation was performed because both the Motor and the NLZ Endo are required cleaning and sterilization after use by user. Cleaning, sterilization, and drying time recommended in the instruction were validated using AAMI TIR 12:2010, AAMI TIR 30:2011, and FDA Reprocessing guidance. The NLZ Motor System met all requirements of the standards. Because the NLZ Motor System is equipped with the overheating risk reduction functions with which the E-STATIS 40 Electric Motor System (K090937) is not equipped, those functions are compared with the functions of the ELECTROtorque TLC 4893 (K103027). The Contra-SAFE function of the subject device has similar features to the SAFEdrive function of the ELECTROtorque TLC 4893 (K103027). The ELECTROtorque TLC 4893 (K103027) does not equipped the functions such as the Contra-Check and Contra-Restriction of the subject device. The performance testing for the Contra-Check and Contra-Restriction does not raise any new concern. Therefore, the NLZ Motor system demonstrated substantial equivalence to the predicates.

j. Biocompatibility

Following biocompatibility test was performed using the Motor and the NLZ Endo:

- Cytotoxicity in accordance with ANSI/AAMI/ISO 10993-5:2009
- Sensitization in accordance with ISO 10993–10:2010
- Irritation in accordance with 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 14457:2012.

All samples were compliant with ISO 14457:2012.

Also, electromagnetic compatibility testing in accordance with IEC 60601-1-2:2014 and electrical safety testing in accordance with AAMI / ANSI/ES60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012 were performed. Those test results indicate that the NLZ Motor System does not raise concern.

Performance testing for the overheating risk reduction functions was performed in accordance with in-house standard. This testing is verification test for software by putting excessive load to the Motor in order to confirm proper Contra-Check judge and motor speed control for Contra-Restriction and Contra-SAFE. The test results indicate that those safety functions do not raise any new concern. In addition, we analyzed temperature increase for returned handpieces due to overheating/burn event and confirmed that the overheating/burn event should be reduced by the overheating risk reduction features.

No animal or clinical testing was performed.

l. Conclusion

The indications for use of the NLZ Motor System is identical to the E-STATIS 40 Electric Motor System (K090937). Although there are some differences in characteristics between the NLZ Motor System and the predicates, a number of performance testing indicated that the NLZ Motor System met the requirement of the standards. Based on above result, we conclude the NLZ Motor System is substantially equivalent to the predicates and does not raise any new safety and effectiveness concern.