June 24, 2024

Nakanishi Inc.
℅ Takahiro Haruyama
President
Globizz Corporation
1411 W. 190th Street
Suite 200
Gardena, California 90248

Re: K233288
Trade/Device Name: NLZ Built-In Motor System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: May 25, 2024
Received: May 28, 2024

Dear Takahiro Haruyama:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Michael E. Adjodha -S

Michael Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233288

Device Name

NLZ Built-In Motor System (NLZ PRO);
NLZ Built-In Motor System (NLZ BF SET);
NLZ Built-In Motor System (NLZ BFB SET);
NLZ Built-In Motor System (NLZ SEL SET);
NLZ Built-In Motor System (NLZ SELB SET);
NLZ Built-In Motor System (Multi Pad 2 SET)

Indications for Use *(Describe)*

The NLZ Built-in Motor System is indicated for use in the field of prophylaxis dentistry, restorative applications including cavity preparation and endodontic therapy, prosthodontics applications such as crown preparations.

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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510(k) #: K233288

510(k) Summary

Prepared on: 2024-06-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Nakanishi Inc
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Applicant Contact	Mr. Masaaki Kikuchi
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Correspondent Name	Globizz Corporation
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Correspondent Contact Telephone	1-310-538-3860
Correspondent Contact	Mr. Takahiro Haruyama
Correspondent Contact Email	register@globizz.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NLZ Built-In Motor System (NLZ PRO); NLZ Built-In Motor System (NLZ BF SET); NLZ Built-In Motor System (NLZ BFB SET); NLZ Built-In Motor System (NLZ SEL SET); NLZ Built-In Motor System (NLZ SELB SET); NLZ Built-In Motor System (Multi Pad 2 SET)
Common Name	Dental handpiece and accessories
Classification Name	Controller, Foot, Handpiece And Cord
Regulation Number	872.4200
Product Code	EBW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K181858	Electric Handpiece Motor EM-12L	EBW
K161213	XSmart iQ	EBW

Device Description Summary

21 CFR 807.92(a)(4)

The NLZ Built-in Motor System is a dental treatment system that is integrated and used in conjunction with dental chair units. It is composed of a motor system, a Multi-Pad, as well as a handpiece (optional) and cord that are compatible with different electric attachments. The motor system has a control unit that works as an electric micromotor which can turn on or off and regulates the speed

of the electric motor by the 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. Depending on the specifications of each chair unit manufacturers, the combination and operation method of the NLZ Built-in Motor System board, harness, and operation method will change.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The NLZ Built-in Motor System is indicated for use in the field of prophylaxis dentistry, restorative applications including cavity preparation and endodontic therapy, prosthodontics applications such as crown preparations.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same. Both devices are indicated for use in preventive dentistry, restorative applications such as cavity preparation and endodontic therapy, and prosthodontic applications including crown preparations.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device is equipped with functionality for driving files in both reciprocating and continuous rotation mode; this feature is absent in the predicate device but present in the reference device.

Similarities: The NLZ Built-in Motor System is a dental treatment system that is integrated and used together with the dental chair unit. It transmits power to compatible handpieces and controls their functions. Software can control functions such as brightness, direction of rotation, speed, and torque. The NLZ Built-in Motor System shares these technical characteristics with the predicate device.

Differences: The differences between the NLZ Built-in Motor System and the predicate device are the ability to drive files in both reciprocating and continuous rotation modes, and the size. However, this ability to drive files in both reciprocating and continuous rotation modes is present in the reference device. The size difference is more a matter of the user's personal preference, which does not affect substantial equivalence.

Therefore, these differences between the NLZ Built-in Motor System and the predicate device do not affect substantial equivalence.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following non-clinical tests were performed to demonstrate substantial equivalence to the predicate device.

Performance Testing: The NLZ Built-in Motor System was subjected to verification and validation testing for motor performance, reprocessing, software, electrical safety, and EMC to support substantial equivalence. The results of these tests demonstrate compliance with the requirements of the following standards and guidance.
- ISO 14457:2017 "Dentistry - Handpieces and motors"
- ISO 17665-1:2006 "Sterilization of health care products - Moist heat - Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices"
- ISO 17664-1:2021 "Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices"
- ISO 17664-2:2021 "Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices."
- IEC 62304:2006+AMD1:2015 "Medical device software - Software life cycle processes"
- IEC 60601-1:2005+AMD1:2012+AMD2:2020 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- IEC 60601-1-2:2014 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"
- FDA guidance document "Dental Handpieces - Premarket Notification [510(k)] Submissions"
- FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"
- FDA guidance document "Content of Premarket Submissions for Device Software Functions"

Biocompatibility: Based on the intended use, the NLZ Built-in Motor System is classified as an External Communicating Device and a device with limited contact (less than 24 hours) with Tissue/Bone/Dentin. Biocompatibility testing was performed to support substantial equivalence. The test results indicate compliance with the requirements of the following standards and guidance:
- ISO 10993-1:2018 "Biological evaluation of medical devices - Part1: Evaluation and testing within a risk management process"
- FDA guidance document "Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk process"

Nonclinical tests concluded that the NLZ Built-in Motor System is substantially equivalent to its predicates.