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

Nakanishi, Inc.
% Diane Rutherford
Submissions Manger
Ken Block Consulting
1201 Richardson Drive, Suite 160
Richardson, Texas 75080

August 15,2017

Re: K163483
Trade/Device Name: Pana Spray Plus
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EFB
Dated: July 31, 2017
Received: August 3, 2017

Dear Diane Rutherford:

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,

Mary S. Runner -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)*

K163483

Device Name
PANA SPRAY Plus

Indications for Use *(Describe)*

PANA SPRAY Plus is a lubricant to be used during routine maintenance of dental and medical surgical handpieces after each patient use and prior to sterilization and is intended for use to clean and lubricate the dental and medical surgical handpieces.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Submitter:	NAKANISHI, INC. 700 Shimohinata Kanuma-shi, Tochigi-ken 322-8666 Japan
Contact Person:	NAKANISHI, INC. Mr. Kimihiko Satoh General Manager, Regulatory Affairs Dept TEL: +81-0289-64-3380 FAX: +81-0289-62-6665 k-satoh@nsk-nakanishi.co.jp
Date Prepared:	August 11, 2017
Trade Name:	PANA SPRAY Plus
Common Name:	Dental handpieces and accessories
Classification Name:	Handpiece, air-powered, dental
Product Code:	EFB Class 1 872.4200
Predicate Devices:	PRIMARY: K131014 - NAKANISHI, INC. PANA SPRAY Plus REFERENCE: K113674 - Handpiece Headquarters Inc, - HPR Inc. Spray & Clean/Maxima/EZcare Handpiece Cleaner & Lubricant
Device Description:	*PANA SPRAY Plus* (PSP) is an alcohol-based general handpiece and air-motor lubricant. The lubricant is introduced into the handpiece through the air-drive pipe or the back end. *PANA SPRAY Plus* can be used for the maintenance of high speed handpieces, low speed handpieces, and air motors and should be used after each patient and prior to sterilization of handpiece and air motors. Additional testing has been conducted to support the claim for cleaning.
Indications for Use:	*PANA SPRAY Plus* is a lubricant to be used during routine maintenance of dental and medical surgical handpieces after each patient use and prior to sterilization and is intended for use to clean and lubricate the dental and medical surgical handpieces.
Summary of Technological Characteristics:	The reason for this submission is to change the previously cleared *Pana Spray Plus* indications (K131014) to include cleaning. The proposed PSP and the predicate *Spray & Clean Handpiece Cleaner & Lubricant* (K113674) both are indicated for cleaning and lubrication of handpieces (including low speed and high speed) and air motors after each patient use and prior to sterilization. The proprietary formulation of the proposed *PANA SPRAY Plus* (PSP) is unchanged from that of the predicate *Pana Spray Plus* (K131014). The proprietary formulation of PSP and both predicates includes lubricant and alcohol components. All are for prescription use only, are provided in aerosol cans and share the method of delivery/principle of operation. Slight variations

in the proprietary chemical formulation between PSP and the predicate Spray & Clean Handpiece Cleaner & Lubricant (K113674) result in slight differences in physical properties. Such slight differences due to proprietary formulations are to be expected and do not impact safety or effectiveness. PSP does not include any accessories.

	New Device	**Primary Predicate Devices**	
Trade Name	*PANA SPRAY Plus*	PANA SPRAY Plus	Spray & Clean Handpiece Cleaner & Lubricant
Description			
510(k) Submitter [Number]	NAKANISHI, INC. [K163483]	NSK America (A subsidiary of NAKANISHI, INC.) [K131014]	HANDPIECE HEADQUARTERS [K113674]
Product Code(s) Regulation	EFB 872.4200	EFB 872.4200	EFB 872.4200
Class	1	1	1
Prescription Only?	Yes	Yes	Yes
Indication for Use	*PANA SPRAY Plus* is a lubricant to be used during routine maintenance of dental and medical surgical handpieces after each patient use and prior to sterilization and is intended for use to clean and lubricate the dental and medical surgical handpieces.	PANA SPRAY Plus is a lubricant intended to be used during routine maintenance of dental and medical surgical handpieces after each patient use and prior to sterilization.	The Dental Handpiece Cleaner and Lubricant is intended to be used during routine maintenance in order to lubricate and clean air-powered Dental Handpieces (including low speed and high speed) and Dental air motors after each patient use and prior to sterilization. The Dental Handpiece Lubricant is intended to be used during routine maintenance in order to lubricate air-powered Dental Handpieces (including low speed and high speed) and Dental air motors after each patient use and prior to sterilization.
Device Design			
Availability:	480 mL Can Case of 6 (480 mL) Cans	480 mL Can Case of 6 (480 mL) Cans	6 oz Can Case of 12 cans
For use with:	High & Low speed handpieces and air motors	High & Low speed handpieces and air motors	High & Low speed handpieces and air motors
Max Temperature	120°F (49°C)	120°F (49°C)	120°F
Contents	Lubricant plus propellant	Lubricant plus propellant	Lubricant plus propellant
Physical State	Aerosol Product	Aerosol Product	Aerosol Product

Summary of Non-clinical Performance Testing:	PSP has undergone reprocessing/cleaning validation to support the claim of cleaning in accordance with FDA guidance titled, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling". In addition, biocompatibility testing was conducted in accordance with ANSI/AAMI/ISO 10993-1 selection of tests for cytotoxicity, sensitization, and irritation. *PANA SPRAY Plus* continues to meet all NAKANISHI, INC. internal requirements for reliability (package vibration, unit drop, and temperature testing) and durability (repeated usage, actual usage, and contra/turbine testing). The test results indicate that *PANA SPRAY Plus* is substantially equivalent to the predicate devices and does not raise new questions of safety or efficacy. Comparison testing was conducted using predicate K113674 to demonstrate performance equivalence for bur extraction force, eccentricity, noise level, and stopping torque with all results being in compliance with ISO 14557.
Conclusion:	NAKANISHI, INC. considers *PANA SPRAY Plus* to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.