October 22, 2021

Nakanishi Inc.
% Gregory Woodard
Ken Block Consulting LLC
800 East Campbell Road, Suite 202
Richardson, Texas 75081

Re: K202120
Trade/Device Name: P300 Attachment
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, And Their Accessories
Regulatory Class: Class II
Product Code: HBE, ERL, HWE
Dated: September 21, 2021
Received: September 22, 2021

Dear Gregory Woodard:

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,

Adam D. Pierce, Ph.D.
Assistant Director
Neurosurgical Devices Team
Division of Neurosurgical, Neurointerventional and Neurodiagnostic Devices
Office of Health Technologies 5, Neurological & Physical Medicine Devices
Office of Product Evaluation & Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

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.

510(k) Number *(if known)*
K202120

Device Name
P300 Attachment

Indications for Use *(Describe)*
The P300 Attachment is intended to be used with electric and pneumatic surgical instruments and cutting accessories for cutting, drilling, removal, and shaping of bone in the procedures of: Neuro, Spine, Orthopedic, ENT, Maxillofacial, and General Surgery.

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.

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."

K202120

510(k) SUMMARY

Submitter:	NAKANISHI INC. 700 Shimohinata Kanuma, Tochigi 322-8666 Japan
Contact Person:	Mr. Masaaki Kikuchi General Manager, Regulatory Affairs Dept. TEL: +81-289-64-7277 FAX: +81-289-62-9738 m-kikuchi@nsk-nakanishi.co.jp
Date Prepared:	October 22, 2021
Submission Type:	Traditional 510(k) Submission
Trade Name:	P300 Attachment
Common Name:	Powered simple cranial drills, burrs, trephines, and their accessories
Classification Name:	Drills, Burrs, Trephines & Accessories (Simple, Powered)
Primary Classification:	HBE 882.4310 Drills, Burs, Trephines & Accessories (Simple, Powered)
Subsequent Classification:	ERL 874.4250 Drill, Surgical, ENT (Electric or Pneumatic), Including Handpiece
Classification for Accessories:	EQJ 874.4140 Bur, Ear, Nose and Throat HWE 878.4820 Instrument, Surgical, Orthopedic, AC-Powered, Motor and Accessory/Attachment GFF 878.4820 Bur, Surgical, General & Plastic Surgery
Predicate Device:	Nakanishi Primado2 Total Surgical System 510(k) Number: K132264 Product Codes: HBC, ERL Product Codes for Accessories: DZI, DZJ, ERL, GEY, HBC, HBE, HWE, GFF, EQJ
Reference Devices:	Stryker MIS Attachments and Cutting Accessories 510(k) Number: K143540 Product Codes: HBE Subsequent Product Code: ERL Stryker Elite and Heavy Duty (HD) Attachments 510(k) Number: K143320 Product Code: HBE Secondary Product Codes: ERL, HBB, DZI
Device Description:	The P300 Attachment is a powered bone cutting and drilling instruments

designed to be used with the Primado2 Total Surgical System (K132264), which provides mechanical power to the attachment. The P300 Attachment is comprised of two families: Standard Attachment 300 and Slim Attachment 300. The Standard Attachment 300 and Slim Attachment 300 consist of angled and straight types of attachments with varying lengths.

The Standard Attachment 300 is an attachment to the Primado2 Total Surgical System that can be in either a straight or angled configuration and comes in 5 different tube lengths, ranging from 12 mm to 79 mm. Accessories compatible with the Standard Attachment 300 include 52 NSK Sterile Cutting Accessories, a STD Attachment Beak, and 4 Irrigation Nozzles.

The Slim Attachment 300 consists of 2 parts, a Slim Attachment Hub that comes in 2 configurations (straight or angled) and a Slim Tube that comes in 8 configurations and varies in tube lengths from 110 mm to 240 mm, and can be straight, curved, or angled. Accessories compatible with the Slim Attachment 300 include 49 NSK Sterile Cutting Accessories, a Slim Tube Beak and a Slim Tube Hood, and 2 Irrigation Nozzles.

The Standard Attachment 300 and Slim Attachment 300 share the same Cleaning Tools for automated cleaning, manual cleaning, and purging.

For both the Standard Attachment 300 and the Slim Attachment 300, the length of the bur can be adjusted in six levels. Both the Standard and Slim attachments include a non-slip surface etching on the grip. The attachments consist of stainless steel, polytetrafluoroethylene, Copper-Beryllium Alloy, fluorocarbon rubber, and PEEK.

Indication for Use:

The P300 Attachment is intended to be used with electric and pneumatic surgical instruments and cutting accessories for cutting, drilling, removal, and shaping of bone in the procedures of: Neuro, Spine, Orthopedic, ENT, Maxillofacial, and General Surgery.

The Indication for Use statement is similar to the predicate device.

Summary of Technological Characteristics:

As with the attachments in the predicate device referenced above, the P300 Attachment includes standard and slim attachments for use with the Primado2 Total Surgical System.

Comparisons with the predicate device show the characteristics of the proposed device to the P300 Attachment to be substantially equivalent to the predicate device. Any differences in the technological characteristics are minor and reflect market strategy and/or perceived user preferences and do not impact the safety, effectiveness, or substantial equivalence of the device. The following table summarizes the comparison of the proposed device with the predicate device for indications for use and technological characteristics.

	Proposed Device	Predicate Device	
Trade Name	P300 Attachment	Primado2	
510(k) Submitter [Number]	Nakanishi, Inc. [K202120]	Nakanishi, Inc. [K132264]	
Indications for Use	The P300 Attachment is intended to be used with electric and pneumatic surgical instruments and cutting accessories for cutting, drilling, removal, and shaping of bone in the procedures of: Neuro, Spine, Orthopedic, ENT, Maxillofacial, and General Surgery.	The Primado2 is an AC-electrically powered total surgical system that is intended for cutting, drilling, sawing, and otherwise manipulating soft tissue, hard tissue, bone, bone cement, prosthesis, implant, and other bone related tissue in a variety of surgical procedures, including but not limited to Cranial (Craniofacial/ Maxillofacial), ENT, Endoscopic /Arthroscopic, Neuro, Orthopedic, Spinal, and General surgical procedures.	SIMILAR
Sterile Cutting Accessories Indications for Use	NSK Sterile Cutting Accessory(ies) is for single use only. This device is intended for use in bone surgery.	NSK sterilized disposable products (burs, saw blades and rasps) are intended for use in bone surgery.	SIMILAR
Product Codes	HBE, ERL Accessories: HWE, GFF, EQJ,	HBC, ERL Accessories: DZI, DZJ, ERL, GEY, HBC, HBE, HWE, GFF, EQJ	SIMILAR
Attachments to be Used with	Primado2	Primado2	IDENTICAL
Types of Attachments	Standard Attachment Series Slim Attachment Series	Slim Attachment Series Super Slim Attachment Series Standard Angled Attachment Series Standard Straight Attachment Series Perforator/Craniotome Attachment Series High Speed Attachment Series Contra Angle Attachment Series	SIMILAR
Energy source to attachments	Mechanical energy from attached motor	Mechanical energy from attached motor	IDENTICAL
Maximum rotation	80,000min^{-1}	80,000min^{-1}	IDENTICAL
Attachment Direct or Indirect Patient Contacting Materials	SUS303, SUS304, SUS316F2, SUS316F2 (TiCN), PEEK	SUS303, SUS304, SUS316F2, SUS316F2 (TiCN), C3604B (NiCr), SUS416F, SUS420J2, C5441B, C5191B, SUS416, SUS420F, ACD34, SUSNSK1 (TiCN), FKM	MODIFIED
Types of Cutting Accessories for Attachments	Burs Drills	Burs Drills Saws Rasps	SIMILAR
Outer Diameters of Cutting Accessories (Burs, Drills)	Φ0.6-7.5 mm	Φ0.6-9.1 mm	SIMILAR
Cleaning Accessories	Yes	No	MODIFIED
Adjustable Bur Length	Yes	No	MODIFIED
Lubrication	PANA Spray Plus (K163483)	PANA Spray Plus (K163483)	IDENTICAL
Cleaning	Automatic Cleaning Or Manual Cleaning	Automatic Cleaning Or Manual Cleaning	IDENTICAL

Sterilization	Pre-Vacuum (Dynamic Air Removal) 132 °C, 4 min. Drying Time: 20 min.	Pre-Vacuum (Dynamic Air Removal) 134 °C, 3 min. Gravity Displacement 132 °C, 15 min	MODIFIED
Use Environment	Temperature: 0 - 40 °C Humidity: 30 - 75 %	Temperature: 0 - 40 °C (no condensation) Humidity: 30 - 75 % Atmospheric Pressure: 700 – 1,060 hPa	MODIFIED
Store and Transportation Environment	Temperature: -10 - 50 °C Humidity: 10 - 85 % Atmospheric Pressure: 500 – 1,060 hPa	Temperature: -10 - 50 °C Humidity: 10 - 85 % Atmospheric Pressure: 500 – 1,060 hPa	IDENTICAL
Biocompatibility Testing	Cytotoxicity Sensitization Intracutaneous Reactivity Acute Systemic Toxicity Material-Mediated Pyrogenicity Indirect (Extract) Hemolysis	Cytotoxicity Sensitization Intracutaneous Reactivity Acute Systemic Toxicity Material-Mediated Pyrogenicity	MODIFIED

The Operation Manuals provide detailed instructions and information for safe and effective use of the device and users are expected to adhere to the instructions and other information. The User's Manual explains how to use the Surgical System and other equipment. Connected medical equipment must comply with IEC 60601-1. Before using the product, be sure to read the manual thoroughly in order to utilize it more effectively.

Performance:

Non-clinical bench performance testing was performed on the P300 Attachment including verification/validation testing to internal functional specifications which demonstrated that the device as safe and effective as the predicate device.

The nature and duration of tissue contact for the device was determined to be limited (≤24 hour) contact with tissue, bone, and cerebrospinal fluid. Evaluations and validations for the P300 Attachment were conducted on the Slim Attachment 300, consisting of parts of each product family that were considered to be worst-case (Slim Attachment Hub P300-1AHS, Slim Tube P300-1T170, Slim Tube Hood P300-1T-H, Irrigation Nozzle P200-IN-1A175, and Bur PDS-1RD170-50), and demonstrate compliance to the applicable standards for biocompatibility (ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2017). Also, indirect (extract) hemolysis testing performed in accordance with ASMT F756:2017 and ISO 10993-4:2017 using the worst-case representative models demonstrated that the P300 Attachment is non-hemolytic. Biocompatibility testing conducted is summarized in the table below.

Test	Result	Conclusion
Cytotoxicity Test / Colony Formation Method [ISO 10993-5]	Cell culture treated with test sample exhibited slight reactivity (Grade 1)	Non-cytotoxic
Cytotoxicity Test / Colony Formation Method [ISO 10993-5] (after maximum cleaning/ disinfection cycle)	Cell culture treated with test sample exhibited no reactivity (Grade 0)	Non-cytotoxic
Sensitization Test / GPMT Method [ISO 10993-10]	The test article extracts showed no evidence of causing delayed dermal contact sensitization.	Non-sensitization

Intracutaneous Reactivity Test [ISO 10993-10]	All animals appeared normal throughout the study. All injection sites appeared normal immediately following injection.	Non-irritability
Acute Systemic Toxicity Test [ISO 10993-11]	There was no mortality or evidence of systemic toxicity from the extracts injected into mice.	Non-toxic
Material-Medicated Pyrogenicity Test [ISO 10993-11]	The total rise of rabbit temperatures during the 3-hour observation period was within acceptable USP requirements. The test article met the requirements for the absence of pyrogens.	Non-pyrogenic
Indirect (Extract) Hemolysis Test [ASTM F756 & ISO 10993-4]	The hemolytic index for the test article extract indicated the hemolytic grade was within the non-hemolytic range.	Non-hemolytic

Testing for the P300 Attachment was also conducted and demonstrated compliance to the applicable standards for reprocessing (ISO 17664:2017, ISO 17665-1:2006, ANSI/AAMI ST79:2017) and sterilization (ISO 11137-2:2013).

The P300 Attachment contains no software or electrical components, so no software or Electrical safety and Electromagnetic Compatibility testing is included in this submission. No clinical data is included in this submission.

Conclusion: The non-clinical bench performance testing data support the safety of the P300 Attachment and the verification and validation demonstrate that the P300 Attachment is as safe and effective as the predicate and reference devices and performs as intended in the specified use conditions. Based on the similarities in intended use, principles of operation, functional design, and non-clinical bench performance testing data, the P300 Attachment is substantially equivalent to the predicate device listed above.