September 19, 2025

Nakanishi, Inc
Prithul Bom
Consultant, Regulatory Technology Services, LLC
1000 Westgate Drive
Saint Paul, MN 55114

Re: K252662
Trade/Device Name: UniBur
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: August 22, 2025
Received: August 22, 2025

Dear Prithul Bom:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.09.19 14:08:50 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252662

Device Name
UniBur

Indications for Use *(Describe)*
UniBur is for single use only. This device is designed to be used with electric surgical instruments manufactured by Nakanishi INC. This device is intended for: cutting, drilling, removal, and shaping of bones in the fields of Neuro, Spine and ENT 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.

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K252662

510(k) SUMMARY

Submitter:	NAKANISHI INC. 700 Shimohinata Kanuma, Tochigi 322-8666 Japan		
Contact Person:	Mr. Masaaki Kikuchi Corporate Vice President, Quality/Regulatory Affairs Division TEL: +81-289-64-7277 FAX: +81-289-62-9738 m-kikuchi@nsk-nakanishi.co.jp		
Date Prepared:	September 19, 2025		
Submission Type:	Traditional 510(k) Submission		
Trade Name:	UniBur		
Classification Name:	Powered Simple Cranial Drills, Burrs, Trephines, and Their Accessories		
Primary Classification:	HBE	882.4310	Drills, Burs, Trephines & Accessories (Simple, Powered)
Subsequent Classifications:	ERL	874.4250	Drill, Surgical, ENT (Electric or Pneumatic), Including Handpiece
	HWE	878.4820	Instrument, Surgical, Orthopedic, AC-Powered, Motor and Accessory/Attachment
Predicate Device:	Nakanishi P300 Attachment; NSK Sterile Cutting Accessories 510(k) Number: K202120 Product Codes: HBE, ERL, EQJ, HWE, GFF		
Reference Devices:	Medtronic MR8 Drill System, Midas Rex MR8 ClearView Tools 510(k) Number: K183515 Product Codes: HBC, HBB, HBE, ERL, HSZ		
Device Description:	The UniBur is a single-use, sterile medical device designed for cutting, drilling, removal, and shaping of bones, used with the Primado2 Total Surgical System (K132264) and used in the fields of neuro, spine, and ENT surgery. The UniBur is designed to be connected to the slim motor handpiece of the Primado2 Total Surgical System. The UniBur has 22 types of product variations based on differences in the length (3 types) and bending angle of the bur guard (3 types), the diameter of the bur for bone cutting (from φ0.6 mm to φ4.5 mm), and the grit size of the diamond embedded in the bur. The UniBur consists of Diamond, Nickel, Stainless steel, Phosphor bronze, Stainless steel, FKM, Polyamide and PTFE.		
Indication for Use:	The UniBur is for single use only. This device is designed to be used with electric surgical instruments manufactured by Nakanishi INC. This device is intended for: cutting, drilling, removal, and shaping of bones in the fields of		

	Neuro, Spine and ENT surgery.
Summary of Technological Characteristics:	The UniBur is a single-use medical device composed of the bur, bur guard, body, irrigation port, and motor connection. By connecting the slim motor handpiece (P200-SMH, P200-SMH-S, P200-SMH-HS) of the Primado2 Total Surgical System, the subject device transmits the rotational motion from the motor handpiece through the clutch mechanism, rotating the bur to perform bone cutting, drilling, and perforation. The subject device is shipped in a sterile condition and is used in the fields of neurosurgery, spine surgery, and ENT surgery. The subject device shares these technical characteristics with the predicate device. These differences are only minor, such as the lower allowable rotational speed of the bur compared to the predicate device and the presence or absence of the bur attachment/detachment mechanism, These differences do not affect the safety, efficacy, or substantial equivalence of the subject device.

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510(k) SUMMARY

Characteristics	Subject Device	Predicate Device	Reference Device	Comparison
Device Name	UniBur	P300 Attachment; NSK Sterile Cutting Accessories	MR8 Drill System, Midas Rex MR8 ClearView Tools	-
510(k) Submitter	Nakanishi Inc.	Nakanishi Inc.	Medtronic Powered Surgical Solutions	-
510(k) Number	K252662	K202120	K183515	-
Product Code	HBE, ERL, HWE	HBE, ERL, HWE	HBC, HBB, HBE, ERL, HSZ	Same
Device Class	II	II	II	Same
Indications for Use	UniBur is for single use only. This device is designed to be used with electric surgical instruments manufactured by Nakanishi INC. This device is intended for: cutting, drilling, removal, and shaping of bones in the fields of Neuro, Spine and ENT surgery.	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. NSK Sterile Cutting Accessory(ies) is for single use only. This device is intended for use, in conjunction with P300 Attachment, in cutting, drilling, removal, and shaping of bone in the procedures of: Neuro, Spine, Orthopedic, ENT, Maxillofacial, and General Surgery.	The Medtronic MR8 Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials in Neurosurgical (Cranial and Craniofacial including craniotomy); Ear, Nose and Throat (ENT), Maxillofacial, Orthopedic, Arthroscopic, Spinal, Sternotomy, and General Surgical Procedures. Additionally, the MR8 Drill System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials during open and minimally invasive spine procedures, which may incorporate application of various surgical techniques during the following lumbar spinal procedures: • Lumbar Microdiscectomy • Lumbar Stenosis Decompression • Posterior Lumbar Interbody Fusion (PLIF) • Transforaminal Lumbar Interbody Fusion (TLIF) • Anterior Lumbar Interbody Fusion (ALIF) • Direct Lateral Interbody Fusion (DLIF) The Midas Rex MR8 ClearView Tools are used only in conjunction with the MR8 Drill System to perform as intended. Please refer to the Midas Rex MR8 Drill System and associated User's Guides for the Indications of Use.	Similar: The Indications for Use of the subject devices remains within the range for the predicate devices, the Indications for Use do not present any new issues of safety or effectiveness.

Characteristics	Subject Device	Predicate Device	Reference Device	Comparison
Device Name	UniBur	P300 Attachment; NSK Sterile Cutting Accessories	MR8 Drill System, Midas Rex MR8 ClearView Tools	-
Surgical fields	UniBur 130: Neuro and Spine Surgery UniBur 70 and UniBur 50 Series: ENT Surgery	Neuro, Spine, Orthopedic, ENT, Maxillofacial, and General Surgery.	Neurosurgical (Cranial and Craniofacial including craniotomy); Ear, Nose and Throat (ENT), Maxillofacial, Orthopedic, Arthroscopic, Spinal, Sternotomy, and General Surgical Procedures.	Similar: The surgical fields of the subject devices remains within the range for the predicate devices, the Indications for Use do not present any new issues of safety or effectiveness.
Patient population	The user shall determine the patient.	The user shall determine the patient.	Candidates for surgical applications stated in the indications for use.	Same: The patient population of the subject device and the predicate device are same.
Indications	UniBur 130: cutting, removal and shaping of bone UniBur 70: ・UBS-RD70C1-30 / UBS-RD70C1-20: cutting, removal and shaping of bone ・UBS-RD70C2-15 / UBS-RD70C2-10: cutting, drilling, removal and shaping of bone ・UBS-RD70C2-06: drilling of bone UniBur 50: ・UBS-RD50C1-30 / UBS-RD50C1-20: cutting, removal and shaping of bone ・UBS-RD50C2-15 / UBS-RD50C2-10: cutting, drilling, removal and shaping of bone ・UBS-RD50C2-06: drilling of bone	Cutting, drilling, removal, and shaping of bone	Incision/cutting, removal, drilling, and sawing of soft and hard tissue, bone, and biomaterials	Similar: The Indications of the subject devices remains within the range for the predicate devices, the Indications for Use do not present any new issues of safety or effectiveness.

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Characteristics	Subject Device	Predicate Device	Reference Device	Comparison
Device Name	UniBur	P300 Attachment; NSK Sterile Cutting Accessories	MR8 Drill System, Midas Rex MR8 ClearView Tools	-
Operation principle	UniBur is used in combination with the control unit, motor, foot control, and accessories of the Primado2 Total Surgical System. The operator uses the foot control or motor hand switch to operate the system. This action sends an electrical signal from the control unit, causing the motor to perform rotational movement. This rotational movement is transmitted to the UniBur, causing the bur attached at the tip of the UniBur to rotate and achieve the intended purpose.	The P300 Attachment is used in combination with the control unit, motor, bur (NSK Sterile Cutting Accessories), foot control, and accessories of the Primado2 Total Surgical System. The operator uses the foot control or motor hand switch to operate the system. This action sends an electrical signal from the control unit, causing the motor to perform rotational movement. This rotational movement is transmitted to the P300 Attachment, causing the bur (NSK Sterile Cutting Accessories) attached at the tip of the P300 Attachment to rotate and achieve the intended purpose.	Electric powered by IPC and Pneumatic powered by Pneumatic Pressure	Similar: Compared to the predicate device, the subject device are replace “Attachment” and “Bur” as one single product with the key subassemblies.
Prescription / over-the counter use	Prescription	Prescription	Prescription	Same
Usage	Single use	Attachment: Reusable Bur: Single use	Single use	Same: The Usage of the subject device and the predicate device are same.
Motor power supply	Electric	Electric	Electric, Pneumatic	Same: The motor power supply of the subject device and the predicate device are same.
Energy source	Mechanical energy from motor	Mechanical energy from motor	Mechanical energy from motor	Same: The energy source of the subject device and the predicate device are same.

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Characteristics	Subject Device	Predicate Device	Reference Device	Comparison
Device Name	UniBur	P300 Attachment; NSK Sterile Cutting Accessories	MR8 Drill System, Midas Rex MR8 ClearView Tools	-
Bur guard style	Angle	Straight, Curved, Angle	Midas Rex MR8 ClearView Tools: Curved, Angle	Similar: The bur guard style of the subject device and the predicate device are similar.
Length of assembled device	111.2 - 192.7 mm	102.5 – 337.5 mm	Unknown	Similar: Compared to the predicate device, the subject device are replace “Attachment” and “Bur” as one single product with the key subassemblies. It does not raise additional issues related to substantial equivalence because of the design of the device. The length of assembled device of the subject devices remains within the range for the predicate device.
Maximum rotation	UBS-RD70C2-06, UBS-RD50C2-06: 10,000 min^{-1} Other Products: 80,000 min^{-1}	80,000 min^{-1}	Unknown	Different: Among the subject devices, UBS-RD70C2-06 and UBS-RD50C2-06 have the lower allowable maximum rotation speed compared to the predicate device.
The presence or absence of the bur attachment/detachment mechanism	absence	presence	absence	Different: The presence or absence of the bur attachment/detachment mechanism differs from the predicate device. However, it is the same as the reference device, supporting substantial equivalence.

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Characteristics	Subject Device	Predicate Device	Reference Device	Comparison
Device Name	UniBur	P300 Attachment; NSK Sterile Cutting Accessories	MR8 Drill System, Midas Rex MR8 ClearView Tools	-
Adjustable bur length	No	Yes	No	Different: The subject device does not have the adjustable bur length mechanism, which makes it different from the predicate device. However, it is the same as the reference device, supporting substantial equivalence.
Shapes of bur	Round	Round, Match head, Reverse taper	Midas Rex MR8 ClearView Tools: Round, Match head	Same: The shapes of bur of the subject device and the predicate device are same.
Style of bur	Diamond	Diamond, Fluted	Midas Rex MR8 ClearView Tools: Diamond, Fluted	Same: The style of bur of the subject device and the predicate device are same.
Diamond grain size of bur	D30, D64, D126, D357	D30, D64, D107, D126, D151, D252, D357, D427, D602	Unknow	Similar: The diamond grain size of bur of the subject devices remains within the range for the predicate device.
Outer diameter of bur	0.6 – 4.5 mm	0.6 – 7.5 mm	Midas Rex MR8 ClearView Tools: 0.5 – 4.5 mm	Similar: The outer diameter of the bur of the subject devices remains within the range for the predicate device.
Bur configurations	One piece, Two piece	One piece, Two piece	Unknow	Same: The bur configurations of the subject device and the predicate device are same.

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Characteristics		Subject Device	Predicate Device	Reference Device	Comparison
Device Name		UniBur	P300 Attachment; NSK Sterile Cutting Accessories	MR8 Drill System, Midas Rex MR8 ClearView Tools	-
Patient Contacting Materials	**Direct**	Bur: Diamond, Nickel, Stainless steel Bur guard: Stainless steel	Attachment: N/A Bur: Diamond, Nickel, Stainless steel	Midas Rex MR8 ClearView Tools: Stainless Steel, Tool Steel, Alloy Steel, Carbide, TDC Coating, Diamond Coating in Nickel Substrate, Titanium Nitride Coating Curved Tube: Stainless Steel Bushing/Bearing Retainers: Stainless Steel Hub: Polymeric Bushing Insert, Cooling Sleeve: Polymeric Lubricant: Nyogel	Different : Conformity to ISO 10993-1 supports substantial equivalence.
	Indirect	Phosphor bronze, Stainless steel, FKM, Polyamide, PTFE	Attachment: Stainless steel, PEEK Bur: N/A		
Sterilization method		Radiation (gamma)	Attachment: N/A (Non-sterile) Bur: Radiation (gamma)	Midas Rex MR8 ClearView Tools: Radiation (gamma)	Same: Sterilization method of the subject device and the predicate device are same.
Shelf life		2 years	Attachment: N/A (Non-sterile) Bur: 5 years	Midas Rex MR8 ClearView Tools: 4 years	Similar: The Shelf life of the subject devices remains within the range for the predicate
Packaging of single use products		Individually packaged and sealed in Tyvek envelopes	Attachment: N/A (Non-sterile) Bur: Individually packaged and sealed in Tyvek envelopes	Midas Rex MR8 ClearView Tools: Individually packaged and sealed in Tyvek envelopes	Same: Packaging of the subject device and the predicate device are same.
Cleaning procedure		N/A (Supplied sterile)	Automatic Cleaning, Manual Cleaning	N/A (Supplied sterile)	Different: The cleaning procedure is not required for the subject device, which makes it different from the predicate device. However, it is the same as the reference device, supporting substantial equivalence.

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Characteristics	Subject Device	Predicate Device	Reference Device	Comparison
Device Name	UniBur	P300 Attachment; NSK Sterile Cutting Accessories	MR8 Drill System, Midas Rex MR8 ClearView Tools	-
Lubrication	N/A	PANA Spray Plus (K163483)	N/A	Different: The lubrication is not required for the subject device, which makes it different from the predicate device. However, it is the same as the reference device, supporting substantial equivalence.
Accessories	No accessories	STD Attachment Beak, Slim Tube Beak, Slim Tube Hood, Irrigation Nozzles	No accessories	Different: The subject device does not use accessories, which makes it different from the predicate device. However, it is the same as the reference device, supporting substantial equivalence.

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. Before using the product, be sure to read the manual thoroughly in order to utilize it more effectively.

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Performance: Non-clinical bench performance testing was performed on the results demonstrated that the device is 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) contact with tissue, bone, and cerebrospinal fluid. Evaluations and validations for the UniBur were conducted using the models identified as worst-case for each test and demonstrate compliance with the applicable standards for biocompatibility (ISO 10993-1:2018). Also, indirect (extract) hemolysis testing performed in accordance with ASMT F756:2017 using the worst-case representative models demonstrated that the UniBur is non-hemolytic. Biocompatibility testing conducted is summarized in the table below.

Biological Endpoint	Standard Used	Pass/Fail Results of Testing with justifications.
Cytotoxicity test	ISO 10993-5	Pass: Grade 0 The test article extract met the requirements of the test since the grade was less than a grade 2.
Sensitization test	ISO 10993-10 GPMT	Pass: Grade 0 The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.
Intracutaneous reactivity test	ISO 10993-23	Pass: The mean score was 0.0 and 0.0 for the SC and SO test article extracts, respectively. The test article met the requirements of the test.
Acute systemic toxicity test	ISO 10993-11	Pass: There was no mortality or evidence of systemic toxicity from the extracts injected into mice. Each test article extract met the requirements of the study.
Material mediated pyrogenicity test	USP, General Chapter <151>, Pyrogen Test	Pass: No single animal showed a temperature rise of 0.5°C or more above its baseline temperature. The test article met the requirements for the absence of pyrogens.
Hemolysis Test	ASTM F756	Pass: The hemolysis test result was below the 2% threshold and therefore considered non-hemolytic.

Testing for the UniBur was conducted and demonstrated compliance to the applicable standard for sterilization (ISO 11137-2:2013).

The UniBur 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 UniBur. The verification demonstrates that the UniBur is as safe and effective as the predicate device and performs as intended under the specified use conditions. Based on the similarities in intended use, principles of operation,

functional design, and non-clinical bench performance testing data, the UniBur is substantially equivalent to the predicate device listed above.