March 11, 2025

Stryker Instruments
Alison Garrad
Senior Staff Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K250374

Trade/Device Name: iBur 3.0mm Diamond Match Head, Distal Bend (8431-107-030D); iBur 3.0mm Precision Round, Distal Bend (8431-009-030); iBur 4.0mm Precision Round, Distal Bend (8431-009-040); iBur 2.0mm Diamond Round, Distal Bend (8431-012-020D); iBur 3.0mm Diamond Round, Distal Bend (8431-012-030D); iBur 4.0mm Diamond Round, Distal Bend (8431-012-040D); iBur 3.0mm Coarse Diamond Round, Distal Bend (8431-013-030DC); iBur 4.0mm Coarse Diamond Round, Distal Bend (8431-013-040DC); iBur 5.0mm Coarse Diamond Round, Distal Bend (8431-013-050DC); iBur 3.0mm Precision Match Head, Distal Bend (8431-107-530)
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, And Their Accessories
Regulatory Class: Class II
Product Code: HBE
Dated: February 10, 2025
Received: February 10, 2025

Dear Alison Garrad:

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: 2025.03.11 16:37:12 -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250374

Device Name
iBur™ Hubs and Cutting Accessories

Indications for Use *(Describe)*
The iBur™ Hubs and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the iBur™ Hubs and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otorhinolaryngology; and Endoscopic applications.

Specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/ Anterior Skull Base/ Endoscopic/ Transnasal/ Transphenoidal, and Orthopedic Spine.

These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.

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.

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Contact Details	
510(k) Owner	Stryker Instruments 1941 Stryker Way, Portage, MI 49002, USA Phone: 269 323 7700
FDA Establishment Registration No.	3015967359
Contact Person	Alison Garrad Senior Staff Regulatory Affairs Specialist Phone: +353-21-4533252 mailto:alison.garrad@stryker.com
Date Submitted	March 11, 2025
Device Name	
Trade Name	Stryker iBur™ cutting accessories
Common Name	Powered simple cranial drills, burrs, trephines, and their accessories
Classification	Class II
Primary Classification	Drills, Burrs, Trephines & Accessories (Simple, Powered) (21 CFR 882.4310, Product code HBE)
Secondary Classification	Drill, Surgical ENT (Electric or Pneumatic) including Handpiece (21 CFR 874.4250, Product code ERL)
Reason for 510(k) Submission	Device modifications, no change to fundamental scientific technology or intended use.
Device Modification	1. Update to bend profile of cutting accessory specifications to alleviate contact pressure at distal tip. 2. Introduction of alignment specification between on cutting accessory distal bushing and nose tube.

Legally Marketed Predicate Device			
510(k) Number	**Product Code**	**Trade Name**	**Manufacturer**
K210377	HBE	Stryker iBur™ Hubs and Cutting Accessories	Stryker Instruments
Reference Device			
510(k) Number	**Product Code**	**Trade Name**	**Manufacturer**

TBA	HBE	Stryker iBur™ Cutting Accessories	Stryker Instruments
Indications for Use		The iBur™ Hubs and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the iBur™ Hubs and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otorhinolaryngology; and Endoscopic applications. Specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/ Anterior Skull Base/ Endoscopic/ Transnasal/ Transphenoidal, and Orthopedic Spine. These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.	
Device Description		iBur™ Cutting Accessories are prescription medical devices that are designed to provide an interface between a cutting accessory and a high speed motor. When used with a motor and a cutting accessory, the iBur™ Hubs are intended to cut, drill, ream, decorticate, shape, dissect, shave and smooth bone in a variety of surgical procedures including the following specialty areas: Neuro, Spine, ENT, Endoscopic. Cutting accessories are single use, sterile devices which have a mount or notch machined at their proximal end and a head with a sharp cutting edge at their distal end. The iBur™ Cutting Accessories are designed to fit the corresponding iBur™ Hubs. The cutting accessories when used with a high speed drill and iBur™ Hubs are intended to cut, drill, ream, decorticate, shape, dissect, shave and smooth bone in a variety of surgical procedures.	
Performance Data (Non-clinical Tests)		The results of the performance testing	

	demonstrate that the functionality, integrity, and safety and effectiveness of the iBur™ Cutting Accessories is sufficient for their intended use and support a determination of substantial equivalence to the predicate devices.
Summary of Performance Testing	Risk Management was conducted in accordance with ISO 14971. Performance testing was conducted on the proposed devices as determined by the risk analysis for the products. The following areas were evaluated: • Temperature and Simulated Use Testing • Design Validation Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the subject devices are sufficient for their intended use and support a determination of substantial equivalence
Clinical Tests	No clinical testing was deemed necessary for this 510(k).

Table 1 Device Numbers and Descriptions

Device Part Number	Device Description
8431-107-030D	iBur™ 3.0mm Diamond Match Head, Distal Bend
8431-009-030	iBur™ 3.0mm Precision Round, Distal Bend
8431-009-040	iBur™ 4.0mm Precision Round, Distal Bend
8431-012-020D	iBur™ 2.0mm Diamond Round, Distal Bend
8431-012-030D	iBur™ 3.0mm Diamond Round, Distal Bend
8431-012-040D	iBur™ 4.0mm Diamond Round, Distal Bend
8431-013-030DC	iBur™ 3.0mm Coarse Diamond Round, Distal Bend
8431-013-040DC	iBur™ 4.0mm Coarse Diamond Round, Distal Bend
8431-013-050DC	iBur™ 5.0mm Coarse Diamond Round, Distal Bend
8431-107-530	iBur™ 3.0mm Precision Match Head, Distal Bend

Table 2 Summary of Substantial Equivalence Table – Regulatory Information

Description		**Stryker iBur™ cutting accessories [Subject]**	**Stryker iBur™ cutting accessories [Predicate K210377]**	**Explanation of Difference**
Regulatory Information	510(k)	TBD	K210377	N/A
	Product Code	HBE	HBE	**Identical**
	Secondary Product Code	ERL	ERL	**Identical**
	Indications for Use	The iBur™ Hubs and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the iBur™ Hubs and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otorhinolaryngology; and Endoscopic applications. Specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/ Anterior Skull Base/	The iBur™ Hubs and Cutting Accessories are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) Console and electric and pneumatic motors. When used with these motors, the iBur™ Hubs and Cutting Accessories are intended to cut bone in the following manner: drilling, reaming, decorticating, shaping, dissecting, shaving, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose, and Throat (ENT)/Otorhinolaryngology; and Endoscopic applications. Specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/ Anterior Skull Base/	**Identical**

Description		Stryker iBur™ cutting accessories [Subject]	Stryker iBur™ cutting accessories [Predicate K210377]	Explanation of Difference
		Endoscopic/ Transnasal/ Transphenoidal, and Orthopedic Spine. These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.	Endoscopic/ Transnasal/ Transphenoidal, and Orthopedic Spine. These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.	
	Classification of Device	Class II	Class II	**Identical**
	Regulation Number	882.4310	882.4310	**Identical**
	Regulation Name	Powered simple cranial drills, burrs, trephines, and their accessories	Powered simple cranial drills, burrs, trephines, and their accessories	**Identical**
	Condition of Use	Single use	Single use	**Identical**
	Type of Use	Prescription Use Only	Prescription Use Only	**Identical**
	Patient Population	General	General	**Identical**
	Contra-indications	None Known	None Known	**Identical**

Table 3 Substantial equivalence Summary Technological Characteristics

Description		**Stryker iBur™ cutting accessories [Subject]**	**Stryker iBur™ cutting accessories [Predicate K210377]**	**Explanation of Difference**
Technological Characteristics	Attachment to Motor interface	SD/PD style interface	SD/PD style interface	**Identical**
	Attachment (Hub) to Motor Locking mechanism	While aligning the dots on the iBur™ hub and motor, slide the iBur™ hub onto the motor until it snaps into place.	While aligning the dots on the iBur™ hub and motor, slide the iBur™ hub onto the motor until it snaps into place.	**Identical**
	Size / length of attachment	Overall device length when cutting accessory assembled into hub 17.1cm.	Overall device length when cutting accessory assembled into hub 17.1cm.	**Identical**
	Nose tube style	Angled	Angled	**Identical**
	Cutting accessory head style offering	Round and Match Head	Round and Match Head	**Identical**
	Cutting accessories diameter head size	2.0mm -5.0mm	2.0mm -5.0mm	**Identical**
	Cutting accessory length	One length 12.5cm	One length 12.5cm	**Identical**

Description		Stryker iBur™ cutting accessories [Subject]	Stryker iBur™ cutting accessories [Predicate K210377]	Explanation of Difference
	No. of flutes on cutting accessories	Two	Two	**Identical**
	Integrated irrigation	Polytube wrapped in a polyurethane heat shrink provides irrigation to the bur head.	Polytube wrapped in a polyurethane heat shrink provides irrigation to the bur head.	**Identical**
	Shelf Life	Diamond Cutting Accessories = 2 year Fluted Cutting Accessories Tool Steel = 2 year	Diamond Cutting Accessories = 2 year Fluted Cutting Accessories Tool Steel = 2 year	**Identical**
	Packaging Configuration	Sealed polybag in a sealed chevron style pouch sterile barrier system.	Sealed polybag in a sealed chevron style pouch sterile barrier system.	**Identical**
	Patient contacting material – cutting accessory	Direct cutting bur head - M2, 440B (Diamond coat). Indirect – Irrigation tubing (polyurethane). Direct – Nose Tube 316L SS and 440C SS, Heat shrink – Polyethylene Terephthalate. Direct - Lubricant cutting accessory - Molykote G-0052FM white bearing Grease.	Direct cutting bur head - M2, 440B (Diamond coat). Indirect – Irrigation tubing (polyurethane). Direct – Nose Tube 316L SS and 440C SS, Heat shrink – Polyethylene Terephthalate. Direct - Lubricant cutting accessory - Molykote G-0052FM white bearing Grease.	**Identical**
	Sterilization	Gamma irradiated	Gamma irradiated	**Identical**

Description		Stryker iBur™ cutting accessories [Subject]	Stryker iBur™ cutting accessories [Predicate K210377]	Explanation of Difference
	Sterility Assurance level	Cutting Accessories: [10-6]	Cutting Accessories: [10-6]	**Identical**
	Principle of operation / mechanism of action	The iBur™ Hubs and cutting accessories are used in conjunction with either an electric or pneumatic motor, CORE Console and a footswitch. When the system is assembled, the surgeon controls the footswitch; this modifies the electrical signal or pneumatic pressure to the motor, controlling the rotational speed of the cutting accessory.	The iBur™ Hubs and cutting accessories are used in conjunction with either an electric or pneumatic motor, CORE Console and a footswitch. When the system is assembled, the surgeon controls the footswitch; this modifies the electrical signal or pneumatic pressure to the motor, controlling the rotational speed of the cutting accessory.	**Identical**
	Motor power supply	Electric and Pneumatic	Electric and Pneumatic	**Identical**
	Speed	5000-75000 rpm	5000-75000 rpm	**Identical**
	Pneumatic pressure recommendations	120 psi (pounds per square inch)	120 psi (pounds per square inch)	**Identical**
	Source of activation	Handswitch and Footswitch	Handswitch and Footswitch	**Identical**

Table 4 Substantial equivalence Summary Overall Design Concept

Description		**Stryker iBur™ cutting accessories [Subject]**	**Stryker iBur™ cutting accessories [Predicate K210377]**	**Explanation of Difference**
Overall Design Concept	Design configuration	Cutting Accessories	Cutting Accessories	**Identical**
	Distal Bend Angle Accessory	Bend profile updated. Bend commences more proximally with a bigger radius of bend creating a more gradual and less pronounced curve.	Device bend commences more distally with smaller radius of bend creating a more obvious curve.	**Similar**
	Nose Tube Alignment Specification	Alignment specification introduced.	Alignment specification not set.	**Similar**
	Line of sight (of surgical site)	Narrow nose tube feature enables line of sight (of surgical site)	Narrow nose tube feature enables line of sight (of surgical site)	**Identical**
	Shank of cutting accessory	0.036” to 0.033”	0.036” to 0.033”	**Identical**

Conclusion / Substantial Equivalence (SE) Rationale

Verification and Validation activities were performed on all characteristics identified in the risk analysis for the proposed modifications to the subject devices. The modifications to the subject devices do not raise any new questions of safety and effectiveness. Moreover, all acceptance criteria were met for the performance testing including temperature testing, demonstrating that the modifications to the subject devices are safe and effective in accordance with their intended use. This assessment supports a conclusion of substantial equivalence.