June 30, 2021

Stryker Corporation
% Allison Garrad
Staff Regulatory Affairs Specialist
Stryker Instruments
1941 Stryker Way
Portage, Michigan 49002

Re: K210377
Trade/Device Name: Stryker iBur hubs and cutting accessories
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, HSZ
Dated: April 4,2021
Received: April 5, 2021

Dear Allison 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 (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
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)*
K210377

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 Core Consolidated Operating Room (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/Transsphenoidal, 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.

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510(k) Summary

This 510(k) Summary for the Traditional 510(k) Submission for the iBur™ Hubs and Cutting Accessories is prepared in accordance with 21 CFR 807.92.

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 Staff Regulatory Affairs Specialist Phone: +353-87-6164723 mailto:alison.garrad@stryker.com
Date	June 30, 2021
Device Name	
Trade Name	Stryker® iBur™ hubs and cutting accessories
Common Name	Powered simple cranial drills, burrs, trephines, and their accessories
Classification	Class II
Review Panel	Neurology
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) Instrument, Surgical, Orthopedic, Ac-Powered Motor And Accessory/Attachment (21 CFR 878.4820, Product Code HWE) Surgical instrument motors and accessories/attachments (21CFR 878.4820, Product Code HSZ)
Reason for 510(k) Submission	Traditional 510(k) – Device modifications and increase in offering with no change to fundamental scientific technology or intended use.
Device Modification	The product line will be expanded to include the following – • Expansion of offering • Integration of irrigation • Integration of nose tube feature into cutting accessory These changes do not change the intended use, indications for use or the fundamental scientific technology of the system.

Legally Marketed Predicate Device			
510(k) Number	**Product Code**	**Trade Name**	**Manufacturer**
K143540	HBE	Stryker® MIS Attachments And Cutting Accessories	Stryker Instruments

Reference Device			
510(k) Number	**Product Code**	**Trade Name**	**Manufacturer**
K191049	HBE	Stryker® MIS and Footed Attachments	Stryker Instruments
K143320	HBE	Stryker® Elite Attachments	Stryker Instruments
These predicate devices have not been the subject of a design related recall.			

Subject Device	
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/Transsphenoidal, 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™ Hubs and 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. The Stryker iBur™ Hubs are available in straight and angled styles and in one length – 12.5cm.

	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™ Hubs and Cutting Accessories is sufficient for their intended use and support a determination of substantial equivalence to the predicate device.
Summary of Performance Testing	Performance testing was conducted on the proposed devices as determined by the risk analysis for the products. The following areas were evaluated: • Functional / Performance Testing • Biocompatibility testing • Sterilization and packaging testing 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 5-1: Model Numbers and Description of proposed devices

Model Numbers	Model Descriptions
8431-107-530	iBur™ 3.0mm Precision Match Head, Distal Bend
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
8442-107-525	iBur™ 2.5mm Precision Match Head, Proximal Bend
8442-107-530	iBur™ 3.0mm Precision Match Head, Proximal Bend
8442-107-025D	iBur™ 2.5mm Diamond Match Head, Proximal Bend
8442-107-030D	iBur™ 3.0mm Diamond Match Head, Proximal Bend
8442-009-030	iBur™ 3.0mm Precision Round, Proximal Bend
8442-009-040	iBur™ 4.0mm Precision Round, Proximal Bend
5407-120-300	iBur™ Straight Hub
5407-120-300A	iBur™ Angled Hub

Table 5-2: Summary of Substantial Equivalence Table

Description		**Stryker iBur™ hubs and cutting accessories [Proposed], K210377**	**Stryker MIS Attachments and Cutting Accessories [Predicate], K143540**	**Comparison**
Regulatory Information	510(k)	K210377	K143540	N/A
	Product Code	HBE	HBE	Same
	Secondary Product Cod	ERL, HWE & HSZ	ERL	Different, the HWE and HSZ product codes have been added as Secondary product codes for the review of K210377, the indications for use for the predicate device list Orthopedic indications but the product codes HWE and HSZ were not added as a secondary codes as part of the predicate submission (K143540)

iBur™ Traditional 510(k)
K210377

	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 forthe 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/	The MIS Attachments 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 MIS Attachments 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.	Same

		Transnasal/ Transsphenoidal, andOrthopedic Spine. These devices are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices.	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	Same
	Regulation Number	882.4310	882.4310	Same
	Regulation Name	Powered simple cranial drills, burrs, trephines, and their accessories	Powered simple cranial drills, burrs, trephines, and their accessories	Same
	Condition of Use	Hubs – reusable Cutting Accessories – single use	Hub – reusable Attachments – reusable Cutting Accessories – single use	Same
	Type of Use	Prescription Use Only	Prescription Use Only	Same
	Patient Population	General	General	Same
	Contra-indications	None Known	None Known	Same
	Usage Hub	Reusable	Reusable	Same
Regulatory Information	Usage Cutting Accessories	Single Use	Single Use	Same

Table 5-3: Substantial Equivalence Summary Comparison Matrix – Overall Design Concept

Description		**Stryker iBur™ hubs and cutting accessories [Proposed], K210377**	**Stryker MIS Attachments and Cutting Accessories [Predicate], K143540**	**Comparison**
Overall Design Concept	Design configuration	Separate components: Hub Cutting accessories	Separate components: Hub Attachments Cutting Accessories	Different
	Attachment configuration	1 piece	2 piece	Different
	Attachment to Motor interface	SD/PD style interface	SD/PD style interface	Same
	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.	Align the dot on the attachment with the dot on the handpiece connector. Press the attachment onto the handpiece until it snaps into the connector.	Same
	Attachment to Cutting Accessory Locking Mechanism	Align the dot on the cutting accessory with the alignment dot on the iBur™ hub and push the cutting accessory into the iBur™ hub until it snaps into place.	Rotate collar to unlock position, Insert the cutting accessory through the attachment tip, Insert cutting accessory to desired exposure level Rotate lock collar to lock position.	Similar.
	Size / length of assembled device	Overall device length when cutting accessory assembled into hub 17.1cm.	Overall device length when cutting accessory assembled into attachment is 17.7cm. Overall device length when cutting	Similar

			accessory assembled into attachment is 20.7cm.	
	Nose tube style	Angled	Straight, Curved, Angled	Same
	Colour bands on attachment	Yes	Yes	Same
	Line of sight (of surgical site)	Narrow nose tube feature enables line of sight (of surgical site)	Telescoping feature enables line of sight (of surgical site)	Similar
	Shank of cutting accessory	.036” to 0.033”	0.046” to 0.058”	Different
	Cutting accessory head style offering	Round and Match Head	Round and Match Head	Same
	Cutting accessories diameter head size	2.0mm -5.0mm	1.5 mm – 5.0 mm	Same
	Cutting accessory length	One length 12.5cm	Two lengths 13 and 16 cm	Different
	No. of flutes on cutting accessories	Two	Two – Eight	Same
	Integrated irrigation	Polytube wrapped in a polyurethane heat shrink provides irrigation to the bur head.	None (may use the optional irrigation sleeve accessory).	Different
	Shelf Life	Diamond Cutting Accessories = 1 year Fluted Cutting Accessories Tool Steel = 1 year	Diamond Cutting Accessories = 5 years Fluted Cutting Accessories Tool Steel = 3 years	Similar

		Hubs – Not applicable as these are reusable devices	Attachments – Not applicable as these are reusable devices	Same

Table 5-4: Substantial Equivalence Summary Comparison Matrix – Material & Processing

Feature	**Stryker iBur™ hubs and cutting accessories [Proposed]**	**Stryker MIS Attachments and Cutting Accessories [Predicate], K143540**	**Comparison**
Non Patient Contacting Material - Hub	Bearing Lubricant Hub	Bearing Lubricant Bearing Lubricant Nose Tube	Similar
Patient contacting material – cutting accessory	Direct cutting accessory Diamond Bur – Stainless Steel 440B (Diamond Coat). Direct Cutting accessory Precision and Match Head Bur – Tool Steel M2.	Direct cutting accessory Diamond Bur – Stainless Steel 440A per ASTM F899. Direct cutting accessory Flutes Bur – M42 Tool Steel per ASTM A600	Similar
Colour band material	Ceramic	Ceramic	Similar
Colour band colourant	Orange	Light Purple (lilac) Brown	Similar
Colour band location	Colour band on the hub	Colour band on the attachment	Same
Sterilization	Cutting accessories – supplied sterile, gamma irradiated	Cutting accessories – supplied sterile, gamma irradiated	Same
	Hub– End-user sterilized (provided non-sterile). Care Instructions has instructions on how to sterilize (moist heat).	Attachment – End-user sterilized (provided non-sterile). IFU has instructions on how to sterilize (moist heat).	Same
Sterility Assurance level	Attachments: 10^{-6}	Attachments: 10^{-6}	Same

	Cutting Accessories: [10-6]	Cutting Accessories: [10-6]	Same
Cleaning Methods	Manual and mechanical (automated)	Manual and mechanical (automated)	Same

Table 5-5: Substantial Equivalence Summary Comparison Matrix – Energy Source

Feature	**Stryker iBur™ hubs and cutting accessories [Proposed]**	**Stryker MIS Attachments and Cutting Accessories [Predicate], K143540**	**Comparison**
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 MIS Attachments 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.	Same
Motor power supply	Electric and Pneumatic	Electric and Pneumatic	Same
Speed	5000-75000 rpm	5000-75000 rpm	Same
Pneumatic pressure recommendations	120 psi (pounds per square inch)	120 psi (pounds per square inch)	Same
Source of activation	Handswitch and Footswitch	Handswitch and Footswitch	Same

Conclusion / Substantial Equivalence (SE) Rationale

A review of all similarities and differences, along with the explanation provided to assert that each difference does not raise new questions of safety or effectiveness, demonstrates that the proposed Stryker iBur™ Hubs and Cutting Accessories are as safe and effective as the predicate, and therefore supports a conclusion of substantial equivalence.