June 14, 2019

Stryker
Paminder Khurmi, RAC
Senior Regulatory Affairs Specialist
4100 E. Milham Ave
Kalamazoo, Michigan 49001

Re: K190172
Trade/Device Name: Stryker Elite Attachments, Stryker Heavy Duty (HD) Attachments
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, HBB, DZI
Dated: March 11, 2019
Received: March 12, 2019

Dear Paminder Khurmi:

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,

Matthew Krueger, M.S.E.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190172

Device Name
Stryker Elite and Heavy Duty (HD) Attachments

Indications for Use *(Describe)*

The Elite and Heavy Duty Attachments 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 Elite and Heavy Duty Attachments and Cutting Accessories are intended to cut bone and bone cement in the following manner: drilling, reaming, decorticating, shaping, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose and Throat (ENT)/Otology/Neurotology/Otorhinolaryngology; Craniofacial and Maxillofacial; Dental; and Endoscopic applications.

The 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.

When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are intended to cut teeth in the following manner: sectioning, segmenting, splitting, fragmenting, extracting, removing, drilling, and reaming.

When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices, or the cutting of screws, metal, wires, pins, and other fixation devices in the following manner: sectioning, deburring, smoothing or shaping of metal, and removing/rounding sharp edges.

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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Section 5. 510(k)Summary

This section provides a summary of 510(k) information in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

510(k) Owner:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, Michigan 49001 USA Ph: +1-269-323-7700 Fax: +1-269-324-5412
Submitter/ Contact Person:	Paminder Khurmi Sr. Regulatory Affairs Specialist Phone: +1-269-389-2264 Fax: +1-269-324-5412 Paminder.Khurmi@Stryker.com
FDA Establishment Registration No.	1811755
Date Submitted:	March 14, 2019

II. DEVICE

Trade Name:	Stryker® Elite and Heavy Duty (HD) Attachments
Common Name:	Surgical Drill Handpieces
Classification name:	Drills, Burs, Trephines & Accessories (Simple, Powered) (21 CFR 882.4310, Product code HBE)
	Drill, Surgical ENT (Electric or Pneumatic) including Handpiece (21 CFR 874.4250, Product code ERL)
	Pneumatic cranial drill motor (21 CFR 882.4370, Product code HBB)
	Drill, Bone, Powered

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	(21 CFR 872.4120, Product code DZI)
Classification:	II

III. PREDICATE DEVICE

510 (K) Number	**Product code**	**Trade name**	**Manufacturer**
K143320	HBE, HBB, ERL, DZI	Stryker® Elite and Heavy Duty (HD) Attachments	Stryker Instruments

IV. SUBJECT DEVICE DESCRIPTION

The Stryker Elite and HD Attachments are used within a system consisting of a variety of devices, including a console, powered motors, and cutting accessories. The attachments connect to the motors and the cutting accessories to complete the system for physician use. The Stryker Elite and HD Attachments are offered for prescription use only. The Elite and HD Attachments are intended to serve as interfaces between powered motors and cutting accessories for the purposes of:

- Cutting bone, bone cement, and teeth;
- Placing or cutting screws, metal, wires, pins, and other fixation devices; and
- Providing a location for the user to hold and grip the device system.

The Elite and HD Attachments are provided in straight and angled configurations. The subject Elite Attachments are offered in the following lengths: 7cm, 12cm, 14cm, 17cm, and 20cm. The Stryker HD Attachments are offered in the following lengths: 9cm and 14cm. The Elite and HD Attachments are powered by, and compatible with, the Stryker electric and pneumatic motors. The attachments are also used with the cutting accessories (burs). All the attachments demonstrate a rotary mode of action by transmitting torque.

The Elite and HD Attachments are made of stainless steel (SST). The attachments display a color band on the outer surface. The color bands serve to enhance the distinction of attachment and cutting accessory compatibility.

The purpose of this submission is to gain clearance for colorant band modification for the Subject Device Attachments color band that exceeds the threshold as per *FDA Guidance, "Deciding When to Submit a 510(k) for a Change to an Existing Device"*.

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V. INDICATIONS FOR USE

TABLE 1: COMPARISON OF INDICATIONS FOR USE

	Subject Device	Predicate Device
Indications for Use	The Elite and Heavy Duty Attachments 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 Elite and Heavy Duty Attachments and Cutting Accessories are intended to cut bone and bone cement in the following manner: drilling, reaming, decorticating, shaping, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose and Throat (ENT)/Otology/Neurotology/Otorhinolaryngology; Craniofacial and Maxillofacial; Dental; and Endoscopic applications. The 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. When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are intended to cut teeth in the following manner: sectioning, segmenting, splitting, fragmenting, extracting, removing, drilling, and reaming. When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices, or the cutting of screws, metal, wires, pins, and other fixation devices in the following manner: sectioning, deburring, smoothing or shaping of metal, and removing/rounding sharp edges.	Same as Subject Device

The Subject Device Indications for Use remains identical to the Predicate Device. The modification described to the Subject Device in this 510(k) does not change the Indication for Use.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Subject Device is compared to the Predicate Device for substantial equivalence of technological characteristics based on the modification described in this submission.

Technological Characteristics

The Color Band location, Attachment to Cutting Accessory Locking Mechanism, and Attachment to Motor Locking Mechanism are identical when comparing the Subject and Predicate Device and, other than the modification described in this submission, all other technological characteristics remain the same between the Subject and Predicate Devices.

The technological characteristics that are not the same between the Subject and Predicate Devices are the color band material and colorant. However, the Subject Device color band material and colorant are similar to those cleared for the Predicate Device, and the different characteristics do not raise different questions of safety and effectiveness.

The change in color band material and colorant on the device does not change the Principle of Operation of the Subject Device compared to the Predicate Device.

The Principle of Operation remains: The Subject Device Attachments are combined with a power source, motor, and cutting accessory to achieve their function; the main function of the Subject Device Attachments is to provide a balanced location for the surgeon to hold and grip the device system, and to transmits torque from the motor to a cutting accessory.

VII. PERFORMANCE DATA

The following testing were conducted, and the data was provided in support of the substantial equivalence determination:

Performance Bench Testing

Verification testing was performed on the Subject Device as dictated by the results of the Risk Analysis, and no new questions of safety and effectiveness were raised. The Subject Device met all pre-defined acceptance criteria. The results of the tests support the substantial equivalence of the Subject Device to the Predicate Device. Testing data from the following was provided in support of the substantial equivalence determination.

- Colorfastness test
- Durability Test

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Biocompatibility Testing

A biocompatibility evaluation was performed following the recommendations of ISO 10993-1: 2018 and FDA Guidance (Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" June 2016) as appropriate for limited exposure (< 24 hours) externally communicating, tissue/bone/dentin devices. The following assessments were completed to further assess the potential risk of the subject device material and colorant modification impacting color additive release.

- Chemical Characterization: ICP-MS
- Toxicological Risk Assessment

The Biocompatibility testing was adopted from K143320

Animal Testing

Animal testing was not required as a basis for substantial equivalence.

Clinical Testing

Clinical testing was not required as a basis for substantial equivalence.

VIII. CONCLUSIONS

The subject device, in comparison with the legally marketed predicate, has the same intended use, indications for use, operating principles, energy source, and functional outputs. Performance testing and risk analysis demonstrate that the device is as safe and effective as the predicate device and does not raise different significant questions of safety and effectiveness.