June 9, 2021

Stryker Corporation
John Chesney
Sr. Principal Regulatory Affairs Specialist
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K211490
Trade/Device Name: Pi Drive 2 Motor, Pi Drive 2 Plus Motor
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL, DZJ, HBE
Dated: May 12, 2021
Received: May 13, 2021

Dear John Chesney:

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,

for Shu-Chen Peng
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K211490

Device Name
Stryker Pi Drive 2 Motor
Stryker Pi Drive 2 Plus Motor

Indications for Use *(Describe)*

The Pi Drive 2 and Pi Drive 2 Plus Motors are intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to Dental, ENT (Ear, Nose and Throat), Neuro, Spine and Endoscopic Applications. They are also usable in the placement or cutting of screws, metals, 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Submitter Information

This Premarket Notification is submitted by:

Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Contact Information

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Email: john.chesney@stryker.com
Date Prepared: 12 May 2021

Device Name

Subject Device Information

Subject Device Information		
Trade/ Proprietary Name		Stryker® Pi Drive 2 Motor Stryker® Pi Drive 2 Plus Motor
Primary	**Regulation Name**	Ear, nose, and throat electric or pneumatic surgical drill.
	Review Panel	Ear, Nose, and Throat
	Product Code	ERL
	Regulation Number	21 CFR 874.4250
	Regulatory Class	Class II
Secondary	**Regulation Name**	Bone cutting instrument and accessories.
	Review Panel	Dental
	Product Code	DZJ
	Regulation Number	21 CFR 872.4120
	Regulatory Class	Class II
	Regulation Name	Powered simple cranial drills, burrs, trephines, and their accessories.
	Review Panel	Neurology
	Product Code	HBE
	Regulation Number	21 CFR 882.4310
	Regulatory Class	Class II

Predicate Device

The legally marketed predicate for the subject devices is detailed as follows.

Predicate Device Information

Predicate Device Trade Name	510(k)	Product Code	Manufacturer
Stryker® Pi Drive Plus Motor	K152641	ERL, HBE, DZJ	Stryker Instruments

Indications for Use

The Pi Drive 2 and Pi Drive 2 Plus Motors are intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drills are intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to Dental, ENT (Ear, Nose, and Throat), Neuro, Spine, and Endoscopic Applications. They are also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

Device Description

The Pi Drive 2 and Pi Drive 2 Plus Motors are non-patient contact, reusable, electric powered (40 VDC) motors that are supplied non-sterile and intended to be to be sterilized by the user prior to each use. The devices are driven by a three-phase, four-pole, brushless DC motor that is housed in a black anodized aluminum body and directly rotates cutting accessories up to speeds of 75,000 RPM. A 4.6 m long cord is integrated into the proximal end of each motor which is used to connect directly to the CORE 2 Console.

The CORE 2 Console is used to supply power to the motors and in conjunction with a foot switch (connected to the console) is used for motor activation and speed control. The Pi Drive 2 Plus contains circuitry that also allows it to be operated using a Stryker handswitch for activation and speed control.

Both motors are identical in technology, functionality, indications for use, and are compatible with the same attachments and cutting accessories. The Pi Drive 2 Plus motor is approximately 10.3 mm longer and weighs 85 grams more than the Pi Drive 2 motor, this additional length accommodates use of the Stryker handswitch.

Comparison of Technological Characteristics

A comparison of the technological characteristics of the subject devices included in the scope of this Special 510(k) with the predicate is included below.

Motor Technological Comparison

DESCRIPTION	Subject Device	Predicate Device
	Stryker® Pi Drive 2 Motor **Stryker® Pi Drive 2 Plus Motor**	**Stryker® Pi Drive Plus Motor (K152641)**
Indications for Use	The Pi Drive 2 And Pi Drive 2 Plus Motors are intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to Dental, ENT (Ear, Nose, and Throat), Neuro, Spine, and Endoscopic Applications. They are also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.	The Stryker Pi Drive Plus Motor is intended for use with the Stryker Consolidated Operating Room Equipment (CORE) System. When used with a variety of attachments and cutting accessories, the drill is intended for use in cutting, drilling, reaming, decorticating, shaping, and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to Dental, ENT (Ear, Nose, and Throat), Neuro, Spine, and Endoscopic Applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.
Classification of Device	Class II	Class II
Primary Product Code	ERL Drill, Surgical, ENT (Electric or Pneumatic) including Handpiece	ERL Drill, Surgical, ENT (Electric or Pneumatic) including Handpiece
Primary Regulation	21 CFR 874.4250 Ear, nose, and throat electric or pneumatic surgical drill	21 CFR 874.4250 Ear, nose, and throat electric or pneumatic surgical drill
Secondary Product Codes	DZJ Driver, Wire, And Bone Drill, Manual HBE Drills, Burrs, Trephines & Accessories (Simple, Powered)	DZJ Driver, Wire, And Bone Drill, Manual HBE Drills, Burrs, Trephines & Accessories (Simple, Powered)
Secondary Regulations	21 CFR 872.4120 Bone cutting instrument and accessories 21 CFR 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories	21 CFR 872.4120 Bone cutting instrument and accessories 21 CFR 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories
Condition of Use	Reusable	Reusable

DESCRIPTION	Subject Device	Predicate Device
	Stryker® Pi Drive 2 Motor **Stryker® Pi Drive 2 Plus Motor**	**Stryker® Pi Drive Plus Motor (K152641)**
Type of Use	Prescription Use Only	Prescription Use Only
Patient Population	General	General
Contraindications	None	None
Principle of Operation	The cutting, drilling, reaming, decorticating, shaping, and smoothing actions are accomplished through the transfer of torque from the motor to the selected attachment mounted on the motor which then transfers the torque to the intended cutting accessory such as a bur, router, or perforator bit.	The cutting, drilling, reaming, decorticating, shaping, and smoothing actions are accomplished through the transfer of torque from the motor to the selected attachment mounted on the motor which then transfers the torque to the intended cutting accessory such as a bur, router, or perforator bit.
Mode of Action	Rotary (transmits Torque)	Rotary (transmits Torque)
Power source	40 V DC Electric Motor connected via cable to CORE 2 Console	40 V DC Electric Motor connected via cable to CORE Console
Diameter of Motor	17mm	17mm
Length of the Motor	98.7mm [Pi Drive 2 Motor] 109mm [Pi Drive 2 Plus Motor]	109mm
Weight of the Motor	315g [Pi Drive 2 Motor] 400g [Pi Drive 2 Plus Motor]	400g
Maximum Speed	75,000 rpm	75,000 rpm
Accessories	• CORE 2 Console • Attachments • Cutting accessories • Irrigation Sleeves / Clips • Extender	• CORE Console • Attachments • Cutting accessories • Irrigation Sleeves / Clips • Extender

DESCRIPTION	Subject Device	Predicate Device
	Stryker® Pi Drive 2 Motor **Stryker® Pi Drive 2 Plus Motor**	**Stryker® Pi Drive Plus Motor (K152641)**
Means of Speed Control	Footswitch [Pi Drive 2 Motor] Hand Switch or Footswitch [Pi Drive 2 Plus Motor]	Hand Switch or Footswitch
Grip Design and Finish	Knurled / Black Diamond Like Carbon (DLC) Coated 455 Stainless Steel	Knurled / 455 Stainless Steel
Cutting Accessories Retention Method	Spring Collar Mechanism in Motor	Spring Collar Mechanism in Motor
Attachment Retention Method	Friction Lock or Mechanical Lock	Friction Lock or Mechanical Lock
Motor Housing Material	Matte Black Anodized 6061-T6 Aluminum ASTM B210/211	Black Anodized 6061-T6 Aluminum ASTM B210/211
Cable Material	Gray Silicone with silicone based anti-friction coating [Pi Drive 2 Motor] Black Silicone with silicone based anti-friction coating [Pi Drive 2 Plus Motor]	Black Silicone with silicone based anti-friction coating
Method of Sterilization	Moist Heat (Steam)	Moist Heat (Steam)
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}
Cleaning Method	Manual and Mechanical (automated)	Manual and Mechanical (automated)
Packaging	Packaged in corrugated box with a retention insert	Packaged in corrugated box with a retention insert

Summary of Non-Clinical Testing

The intended use of the subject devices and predicate are identical, and their technological characteristics are similar. The subject devices are a line extension of the predicate and utilize the same design and operating principles. The device modifications do not raise any new or different questions of safety and effectiveness.

Risk management was conducted in accordance with ISO 14971 and did not identify any new or unacceptable risks when compared to the predicate. The following testing was conducted to demonstrate that the modifications to the subject devices are as safe and effective as the predicate.

- Motor Reliability Life
- Electrical Reliability
- IEC 60601-1 Electrical Safety
- IEC 60601-1-2 EMC / EMI Testing
- Packaging Integrity
- Device Validation Summary

Results of these tests demonstrate that the functionality, integrity, and safety and effectiveness of the subject devices are sufficient for their intended use, indications for use and support a determination of substantial equivalence.

Summary of Clinical Testing

Clinical testing was not required for this Special 510(k).

Conclusion

The subject devices have the same indications for use, intended use, principle of operation, functional characteristics, and use applications. The modifications introduced raise no new or different issues of safety and effectiveness and testing has demonstrated substantial equivalence to the predicate device