DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 15, 2017

Stryker Corporation
Nicholas Werner
Senior Staff Regulatory Affairs Specialist
4100 E. Milham Ave.
Kalamazoo, MI 49001

Re: K171840
Trade/Device Name: Stryker Consolidated Operating Room Equipment (CORE) 2 Console
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose, and Throat Electric or Pneumatic Surgical Drill
Regulatory Class: Class II
Product Code: ERL
Dated: June 19, 2017
Received: June 20, 2017

Dear Nicholas Werner:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171840

Device Name
Stryker Consolidated Operating Room Equipment (CORE) 2 Console

Indications for Use *(Describe)*

The Stryker Consolidated Operating Room Equipment (CORE) 2 Console is intended for use in the 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, Throat), neuro, spine, and endoscopic applications. The console is also usable in the placement or cutting 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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Section 5 – 510(k) Summary

Prepared: 19 June 2017

I. SUBMITTER

Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
Phone: 269-389-2971

Contact: Nicholas Werner

II. DEVICE

Name of Device:	Stryker Consolidated Operating Room Equipment (CORE) 2 Console
Common/Usual Name:	Console
Regulation Numbers:	21 CFR 874.4250
Regulation Name:	Drill, Surgical, ENT (Electric or Pneumatic)
Regulatory Class:	II
Product Codes:	ERL

III. PREDICATE DEVICE

Primary Predicate	Stryker Consolidated Operating Room Equipment (CORE) System, K112593

IV. DEVICE DESCRIPTION

The Stryker CORE 2 Console is a modernization of the currently marketed CORE Console. The CORE 2 Console supplies power to a variety of devices, which include small and large bone handpieces, footswitches, and a bone mill. The CORE 2 Console contains a touch screen graphical user interface (GUI), which allows the user to program a number of customized settings related to the connected devices and irrigation.

V. INDICATIONS FOR USE

The Stryker Consolidated Operating Room Equipment (CORE) 2 Console is intended for use in the 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, throat), neuro, spine, and endoscopic applications. The console is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table identifies technological characteristics shared between the Predicate and Subject device:

Section 5 – 510(k) Summary

	Predicate Device	Subject Device
Indications for Use	Intended for use in the 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, throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices.	Same
Contraindications	None known	Same
For use with	Various small and large bone handpieces, footswitches, and a bone mill.	Same
Patient Contact	No direct or indirect patient contact	Same
Power Output	Handpiece port output voltage: 40V Footswitch port output voltage: 5V	Same
Electrical Isolation Type	Class I, Type BF Applied Part	Same
Electrical Safety & EMC	Tested and compliant with IEC 60601-1, IEC 60601-1-2	Same
Irrigation	Irrigation Pump and Pump Controller – A DC brush motor with an optical encoder is used to create a peristaltic pump. A micro-controller measures motor speed from the encoder and adjusts the supply voltage to the motor appropriately to achieve the desired speed. Start, stop, and speed indications are received from the main processor.	Same
User Interface	A color LCD screen allows the user to set the desired operating parameters. Touchscreen interface with GUI workflow.	Same

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	Predicate Device	Subject Device
Software	Microprocessor	Same
Wireless Tag Technology (RFID)	Certain accessories are recognized and identified on the console screen.	Same

The following differences between the subject and predicate device were considered in relation to the substantial equivalence determination:

- CORE 2 handpiece and footswitch ports have illumination rings that serve as secondary identifiers for mapping.
- CORE 2 has a modified GUI workflow designed to be less complex.
- CORE 2 has a capacitive touchscreen interface.
- Users are able to transfer saved use-preference profiles via USB between consoles if desired.
- The software of CORE 2 was rewritten to accommodate internal circuitry redesigns.

VII. PERFORMANCE TESTING

The following performance testing was conducted to support substantial equivalence:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the CORE 2 Console. The device complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Mechanical Testing

The following design verification activities have been performed to ensure the correct functionality of the console as it has been specified:

- Reliability and Use Life Testing
- Compatibility Testing (with defined accessories)
- Performance testing for torque mapping capability and capacitive touchscreen

Human Factors Evaluation

Human factors analysis and usability testing was performed in support of the Substantial Equivalence determination and in accordance with FDA's Guidance for Industry and FDA Staff, "Applying Human Factors and Usability Engineering to Optimize Medical Device Design" and IEC 62366-1 "Medical Devices – Application of Usability Engineering to Medical Devices."

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Biocompatibility
Biocompatibility data is not required to support a Substantial Equivalence determination as the CORE 2 Console is identical to the predicate device in that there are no components with direct or indirect patient contact.

Animal Study
Not Applicable – data from animal studies was not provided to support the Substantial Equivalence determination. Animal studies are not required to demonstrate safety or feasibility of the CORE 2 Console.

Clinical Studies

Not Applicable – data from clinical studies was not provided to support the Substantial Equivalence determination. Clinical studies are not required to demonstrate safety or feasibility of the CORE 2 Console.

VIII. CONCLUSIONS

The differences that exist between the CORE 2 Console and its predicate do not raise different questions of safety or effectiveness. The results of non-clinical performance testing demonstrate that the CORE 2 Console will perform as intended and is substantially equivalent to the predicate device which is marketed for the same intended use.