July 12, 2019

Stryker Endoscopy
Mr. Justin Florence
Regulatory Affairs Specialist
5900 Optical Court
San Jose, California 95138

Re: K191259
Trade/Device Name: Stryker CrossFlow Integrated Arthroscopy Pump
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: May 9, 2019
Received: May 10, 2019

Dear Mr. Florence:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation & 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)*
K191259

Device Name
Stryker CrossFlow Integrated Arthroscopy Pump

Indications for Use *(Describe)*
The Stryker CrossFlow Integrated Arthroscopy Pump is a dual arthroscopic pump system intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.

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

I. SUBMITTER

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San Jose, CA 95138

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Email: justin.florence@stryker.com

Contact Person: Justin Florence
Date Prepared: May 9, 2019

II. DEVICE

Name of Device: Stryker CrossFlow Integrated Arthroscopy Pump
Common or Usual Name: Arthroscopic Pump, Tubing Sets and Accessories
Classification Name: Arthroscope (21 CFR 888.1100)
Regulatory Class: II
Product Code: HRX

III. PREDICATE DEVICE

Stryker CrossFlow Integrated Arthroscopy Pump, K123441
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Stryker CrossFlow Integrated Arthroscopy Pump (CrossFlow) is a microprocessor-controlled dual (inflow and outflow) pump system designed to provide liquid distention and irrigation of joint cavities and aspiration of liquids out of the joint cavities during diagnostic and operative arthroscopy. Both the irrigation and aspiration pump of the device function according to the peristaltic principle. The Stryker CrossFlow Integrated Arthroscopy Pump consists of the following main components: console housing, power supply, two peristaltic pumps, three pinch valves, and a touch-screen display panel. The device is to be used with specially designed irrigation and aspiration tube sets and can be operated by remote hand and foot controls. A constantly-performed pressure sensing algorithm controls the value of the actual pressure in the joint cavity as compared to the set pressure determined by the user.

The proposed software modification consists of a graphical user interface (GUI) aesthetic update and the addition of a temperature estimation algorithm and on-screen indicator.

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The algorithm analyzes data features to estimate the in-joint temperature and implements mitigating actions to reduce the likelihood of high temperatures.

V. INTENDED USE/INDICATIONS FOR USE

The Stryker CrossFlow Integrated Arthroscopy Pump is a dual arthroscopic pump system intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle, and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristic	**Subject Device** *Stryker CrossFlow Integrated Arthroscopy Pump*	**Predicate Device** *Stryker CrossFlow Integrated Arthroscopy Pump (K123441)*
Intended Use/Indications for Use Statement	Same as predicate device.	The Stryker CrossFlow Integrated Arthroscopy Pump is a dual arthroscopic pump system intended to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle and wrist joint cavities and fluid suction during diagnostic and operative arthroscopic procedures.
Contraindications	Same as predicate device.	The use of the Stryker CrossFlow Integrated Arthroscopy Pump is prohibited whenever arthroscopy is contraindicated.
Product Code(s)	Same as predicate device.	HRX
Pump Mechanism	Same as predicate device.	Peristaltic
Pump Type	Same as predicate device.	Inflow/Outflow, Inflow Only
Operating Principle	Same as predicate device.	The device is controlled by software and microelectronics that execute control algorithms that ensure the set pressure is being achieved within the patient's joint.
Roller Wheel	Same as predicate device.	The device has internally-mounted roller wheels that interface with cassettes that are part of the disposable, single-use tube sets.
EMC/Electrical	Same as predicate device.	IEC 60601-1-2 IEC 60601-1 IEC 60601-2-18

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Design	Same as predicate device.	Pump consists of the following main components: - console housing - power supply - two peristaltic pumps - three pinch valves - touch-screen display panel
Energy Source	Same as predicate device.	Supply voltage provided to the console is that of a typical business or hospital environment.

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Discussion of Similarities and Differences

The core functionality of the Stryker CrossFlow Integrated Arthroscopy Pump, as cleared per K123441, remains unchanged. Similarly, the indications for use and intended use remain unchanged.

The changes described in this premarket notification are entirely contained within the software. No hardware changes are being implemented. The proposed software modification implements a graphical user interface (GUI) aesthetic update and the addition of a temperature estimation algorithm and on-screen indicator.

VII. PERFRMANCE DATA/NON-CLINICAL TESTING

Design verification and validation testing were performed on the Stryker CrossFlow Integrated Arthroscopy Pump as a result of the risk analysis and product requirements. Testing included software verification testing, bench performance testing as well as design validation. Software verification testing was conducted to ensure the newly added temperature estimation algorithm and resulting mitigating actions performed according to specification. Bench performance testing was conducted to ensure the temperature estimation algorithm meets accuracy specifications and reduces the occurrence of high fluid temperature. Design validation testing was conducted in a simulated-use environment by surgeon and nurse users. Users were successfully able to navigate the updated GUI and use the CrossFlow as intended.

Software testing

Software 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 to be of "moderate" level of concern since a failure or latent flaw in the software could result in minor injury to the patient or user of the device.

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Mechanical testing

Mechanical functionality testing included the following to ensure the device design meets user needs in the environment of use:

- Temperature accuracy testing
- Temperature limit testing
- Simulated-use testing

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Stryker CrossFlow Integrated Arthroscopy Pump and results provided as part of the original 510(k) submission, K123441. The CrossFlow complies with the IEC 60601-1 standard for safety, the IEC 60601-1-2 standard for EMC, and the IEC 60601-2-18 standard for safety of endoscopic equipment.

Animal Study

No animal testing was conducted to determine the safety and effectiveness of the Stryker CrossFlow Integrated Arthroscopy Pump.

Clinical Studies

No human clinical testing was conducted to determine the safety and effectiveness of the Stryker CrossFlow Integrated Arthroscopy Pump.

VIII. CONCLUSIONS

The technological characteristics and intended use of the Stryker CrossFlow Integrated Arthroscopy Pump remains unchanged and therefore is substantially equivalent to the predicate – the Stryker CrossFlow Integrated Arthroscopy Pump (K123441). The proposed software modification does not raise different questions of safety and effectiveness of CrossFlow. The results of the non-clinical testing conducted supports the safety of the device and demonstrates that CrossFlow performs as intended in the specified use conditions.