DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 31, 2016

Stryker Corporation
Somi Ekwealor
Regulatory Affairs Analyst
5900 Optical Ct
San Jose, California 95138

Re: K151932
Trade/Device Name: Stryker Crossflow Day-Use Inflow Cassette Tubing and Patient-Use Tubing
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: February 25, 2015
Received: February 29, 2016

Dear Somi Ekwealor:

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 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 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: Stryker® CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing

510(k) Number (if known): K151932

Indications for Use:

The Stryker CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing are used in conjunction with the CrossFlow Integrated Arthroscopy Pump (K123441) to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle, and wrist joint cavities during diagnostic and operative arthroscopic procedures.

Prescription Use___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (Part 21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

1. General Information

510(k) Sponsor	Stryker Endoscopy
Address	5900 Optical Court San Jose, CA 95138
FDA Registration Number	2936485
Correspondence Person	Mr. Somi Ekwealor, MSRS, RAC Regulatory Affairs Analyst Stryker Endoscopy
Contact Information	Email: somi.ekwealor@stryker.com Phone: (408) 754-2356 Fax: (408) 754-2507

2. Device Identification

Proposed Device:

Proprietary Name	Stryker® CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing
Common Name	Irrigation Tubing Sets
Classification Name	Arthroscope
Regulation Number	21 CFR 888.1100
Product Code	HRX
Regulatory Class	II

Predicate Devices:

Proprietary Name	Arthrex Continuous Wave III Arthroscopy Pump (Tubing Only)
Common Name	Pump
Premarket Notification	K024291
Classification Name	Arthroscope
Regulation Number	21 CFR 888.1100
Product Code	HRX
Regulatory Class	II

Reference Device:

Proprietary Name	Stryker CrossFlow Arthroscopy Pump
Common Name	Pump
Premarket Notification	K123441
Classification Name	Arthroscope

Regulation Number	21 CFR 888.1100
Product Code	HRX
Regulatory Class	II

A reference device is used in this premarket notification to support scientific methodology because the reference device and proposed device share materials and test methods. The proposed device is also an accessory to, and indicated for use with the reference device. The reference device is discussed throughout this premarket notification when discussing the device description, indications for use, and performance testing.

3. Device Description

The Stryker CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing (hereafter referred to as "proposed device") is an accessory to the FDA-cleared CrossFlow Integrated Arthroscopy Pump, cleared under K123441, which provides fluid to the surgical site. CrossFlow Day-Use Inflow Cassette Tubing includes an inflow cassette with spikes for irrigation fluid units and connector. The Patient-Use Tubing includes a connector that attaches the Patient-Use Tubing to Day-Use Tubing, and luer-lock connector that attaches the Patient-Use Tubing to an inflow cannula. The Stryker CrossFlow Day-Use Inflow Cassette Tubing is a 24-hour multi-patient device that remains in the arthroscopy pump throughout a day of cases (no more than 10 cases, 8 hours of active use, or 24 hours from the point of first use). Day-Use Inflow Cassette Tubing provides an alternate to complete replacement of the irrigation tubing after each patient. The backflow check valve of the Patient-Use Tubing prevents contaminated fluid from reaching the Day-Use Tubing and permits its use for a day of cases. Patient-Use Tubing is a single-use device that is discarded after every case.

4. Indication for Use

The Stryker CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing are used in conjunction with the CrossFlow Integrated Arthroscopy Pump (K123441) to provide fluid distension and irrigation of the knee, shoulder, hip, elbow, ankle, and wrist joint cavities during diagnostic and operative arthroscopic procedures.

5. Comparison of Technological Characteristics with the Predicate Device

The Stryker CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing and predicate devices tubing are similar in technological characteristics and design.

Stryker CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing are substantially equivalent to the predicate devices. In accordance with 21CFR807.92(a)(6) a summary of how the technological characteristics of the proposed device compares to the predicate device is

provided below. A complete comparison of technological characteristics between the proposed and predicate devices is provided in Section 12 – *Substantial Equivalence Discussion*.

Differences between the Proposed and Predicate Devices

Characteristics	Proposed Devices	Predicate Devices (K024291)
Inner Diameter of Tubing (mm)	Day-Use Tubing: 6.20±0.05 Patient-Use Tubing: 6.20±0.05	Arthrex Reduce Tubing, Pump Tubing (AR-6411): 4.83 Reduce Tubing, Patient Tubing (AR-6241): 6.35
Tubing Length (mm)	Day-Use Tubing: 1200 Patient-Use Tubing: 2800	Arthrex Reduce Tubing, Pump Tubing (AR-6411): 2310 Reduce Tubing, Patient Tubing (AR-6241): 2347
Pressure Sensing Mechanism	Internal pressure dampening membrane	External pressure chamber
Tubing Cassette Loaded	Yes	No
Cassette Material	ABS	N/A
RFID	Yes	No
Disinfection Method	Included and in accordance with Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – March 17, 2015	None
Device Lifetime Claim	Single day's cases (no more than 10 cases, 8 hours of active use, or 24 hours from point of first use)	1 surgical day

Tubing Specifications:

The difference in inner diameter is negligible as verification testing provided in this submission demonstrates that this difference has no effect on the safety or effectiveness of the device.

The difference in length of the tubing is also negligible as verification testing provided in this submission demonstrates that the difference has no effect on the safety or effectiveness of the device.

These minor differences in the proposed device raise no new questions of safety or effectiveness, therefore the proposed device is substantially equivalent to the predicate device.

Pressure Sensing Mechanism:

The proposed device aids the CrossFlow Integrated Arthroscopy pump in measuring pressures in the joint space via a pressure dampening chamber housed in the cassette of Day-Use Inflow Cassette Tubing. The predicate device contains an external pressure chamber that acts similarly to the pressure dampening chamber in sensing pressure fluctuations.

This minor difference in how pressure is measured in the proposed device raises no new questions of safety or effectiveness, therefore the proposed device is substantially equivalent to the predicate device.

Tubing Cassette

Both devices are accessories to irrigation pumps that operate on the peristaltic principle where roller wheels are spun against soft tubing to create the flow of fluid within the tubing. The devices are different in how the tubing interfaces with the roller wheels of the pump. The predicate device requires the user to manually place the tubing inside the console and around the roller wheels while the proposed device simply requires the user to insert a cassette containing the peristaltic tubing into the cassette.

The cassette includes a Radio-frequency Identification (RFID) component that allows the CrossFlow Arthroscopy Pump to recognize tubing cassettes as either new or expired. The predicate device does not include any technology that allows the pump to differentiate between new tubing and tubing that has been used after the intended product lifetime (one surgical day).

This minor difference in the proposed device raises no new questions of safety or effectiveness, therefore the proposed device is substantially equivalent to the predicate device.

Disinfection

A disinfection method was developed for the proposed device to prevent cross-contamination of the connector between cases. Inadvertent and undetected contamination of the device is prevented by disinfecting the connector after each case. Complete disinfection instructions are provided in Section 13 – Labeling. The predicate device labeling does not contain disinfection instructions to ensure safe reprocessing of the device.

This difference in the proposed device raises no new questions of safety or effectiveness, therefore the proposed device is substantially equivalent to the predicate device.

Device Lifetime

The proposed device can be used for a single day's cases – no more than 10 cases, 8 hours of active use, or 24 hours from point of first use, which is based on data from a high case-volume day at a high volume arthroscopy surgery center. This claim is supported by the performance testing. Full test summaries and results can be found in Section 18 – Performance Testing – Bench. The predicate device is also intended to be used for a single day's cases or one surgical day however they provide no definition of one surgical day. Based on the data obtained, one surgical day will not exceed 8 hours of active use or 10 cases performed within a 24 hour period.

This difference in the proposed device labeling raises no new questions of safety or effectiveness, therefore the proposed device is substantially equivalent to the predicate device.

Any technological differences between the Stryker CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing and the predicate devices do not raise new questions of safety or effectiveness.

6. Performance Testing

The Stryker CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing were evaluated in accordance with internal design specification and with the applicable performance standards as required by the risk analysis. The assessment of non-clinical performance data supports the substantial equivalence determination. The following non-clinical tests were conducted and are summarized in this submission:

Biocompatibility was assessed in accordance with ISO 10993-1:2009 "Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing within a Risk Management Process" and related collateral standards for direct and indirect patient contacting materials (see Section 15 – Biocompatibility).

Sterilization was assessed in accordance with ISO 11135:2014 – "Sterilization of health-care products - Ethylene Oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices". Sterilization residuals were assessed in accordance with ISO 10993-7:2008 – "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals" (see Section 14 – Sterilization and Shelf Life).

Bench performance testing was conducted to ensure that the device functioned as intended and met design specifications and acceptance criteria based off of predicate data. The following performance tests were executed in support of the substantial equivalence determination:

Test	Description	Results
Microbial Ingress	Confirms ability to maintain sterility of inner tubing during lifetime of device	Pass
Day-Use Inflow Cassette Tubing Disinfection	Confirms safety of the device over multiple uses by achieving disinfection of the Day-Use Tubing to Patient-Use Tubing connection	Pass
Backflow Valve	Confirms no cross contamination occurs between cases by analyzing if microorganisms can breach the backflow valve	Pass
Backflow Valve Limit of Quantification	Measures limit of quantification for backflow valve test method	Pass
Backflow Valve Time to Close	Ensures adequate closure of backflow valve to prevent backwards movement of fluid	Pass
Backflow Valve Failure	Confirms complete backflow valve failure is not a risk to the patient	Pass
Regurgitation	Ensures fluid moving in the opposite direction to the normal direction does not pose risk of cross contamination	Pass
General requirements and performance	Verified all components against their design specifications	Pass
Viral Pathogens	Confirms no cross contamination occurs between cases by analyzing if viral pathogens can breach the backflow valve based on model system	Pass
Biocompatibility	Verified the biocompatibility of all patient contacting materials in accordance with ISO 10993-1:2009	Pass
Sterilization	Ensured the EO sterilization process for all single-use, sterile components in accordance with ISO 11135-1:2014 to a sterility assurance level (SAL) of 10^{-6} and verified that the EO and ECH residuals are within the limits defined in ISO 10993-7:2008	Pass
Real Time Aging	Verified functionality of all single-use, sterile components and integrity of all packaging after claimed shelf life	Pass

Test results obtained verified the safety and effectiveness of the device per design specifications and applicable standards when compared to bench testing. The test results support the substantial equivalence of the Stryker CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing compared to the predicate devices. Full test summaries and results can be found in Section 18 – Performance Testing – Bench.

7. Nonclinical Testing

When the proposed device is in use certain components will indirectly contact the patient. The materials used were analyzed in accordance with ISO 10993-1:2009. Test results show that the device meets all applicable requirements.

The nonclinical tests conducted and referenced in this premarket notification show that the proposed device meets or exceeds the performance requirements, and demonstrate the device is as safe, as effective, and performs as well as or better than the predicate device based on competitor test data.

8. Conclusion

The proposed and predicate devices are similar in design and performance specifications. Clinical testing was not required to demonstrate substantial equivalence. Based on the evaluation of the indication for use, technological characteristics, performance testing, nonclinical testing, and comparison to the predicate devices, the Stryker CrossFlow Day-Use Inflow Cassette Tubing and Patient-Use Tubing raises no new questions of safety and effectiveness when compared to the predicate device and is thus considered substantially equivalent.