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

October 23, 2014

Stryker Endoscopy
Mr. Dave Yungvirt
Third Party Review Group, LLC
45 Rockefeller Plaza, Suite 2000
New York, New York 10111

Re: K142603
Trade/Device Name: Stryker Precision HD Camera System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GJC
Dated: October 9, 2014
Received: October 10, 2014

Dear Ms. Yungvirt:

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" (21CFR 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,

David Krause -S

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

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)*
K142603

Device Name
Stryker Precision HD Camera System

Indications for Use *(Describe)*
The Stryker Precision HD Camera System is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope/endoscope/arthroscope is indicated for use.

A few examples of the more common endoscopic surgeries are listed below.
- laparoscopic cholecystectomy
- laparoscopic hernia repair
- laparoscopic appendectomy
- laparoscopic pelvic lymph node dissection
- laparoscopically assisted hysterectomy
- laparoscopic and thorascopic anterior spinal fusion
- anterior cruciate ligament reconstruction
- knee arthroscopy
- shoulder arthroscopy
- small joint arthroscopy
- decompression fixation
- wedge resection
- lung biopsy
- pleural biopsy
- dorsal sympathectomy
- pleurodesis
- internal mammary artery dissection for coronary artery bypass
- coronary artery bypass grafting where endoscopic visualization is indicated
- examination of the evacuated cardiac chamber during performance of valve replacement

The users of the camera are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) SUMMARY

1) General Information

510(k) Sponsor	Stryker Endoscopy
Address	5900 Optical Court San Jose, CA 95138
FDA Registration Number	2936485
Correspondence Person	Angela Wong Staff Regulatory Affairs Analyst Stryker Endoscopy
Contact Information	Email: angela.wong@ stryker.com Phone: (408) 754-2737
Date Prepared	10 September 2014

2) Proposed Device

Proprietary Name	Stryker Precision HD Camera System
Common Name	3-Chip Video Camera
Classification Name	Laparoscope, General and Plastic Surgery
Regulation Number	21 CFR 876.1500
Product Code	GCJ
Regulatory Class	II

3) Predicate Device

Proprietary Name	Stryker 1488 HD Video Camera with Infrared Compatibility
Common Name	3-Chip Video Camera
Premarket Notification	K132785
Classification Name	Laparoscope, General and Plastic Surgery
Regulation Number	21 CFR 876.1500
Product Code	GCJ
Regulatory Class	II

Stryker® Precision HD Camera System. 510(k) Summary

4) Device Description

The Stryker Precision HD Camera Systems (hereafter referred to as "proposed device") is an endoscopic camera system that is used together with an endoscope to view endoscopic surgical sites on video monitors. The system consists of a Camera Control Unit (CCU), a Coupler, and a Camera Head with an integral cable that connects to the CCU. The optical image is transferred from the surgical site to the camera head by a variety of rigid and flexible scopes that are attached to the camera head using an optical coupler or by direct connection. Sterilization of the Coupler and Camera Head is required before use. The Coupler and Camera Head can be sterilized using steam sterilization.

5) Indication for Use

The Stryker Precision HD Camera System is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope/endoscope/arthroscope is indicated for use.

A few examples of the more common endoscopic surgeries are listed below.

- laparoscopic cholecystectomy
- laparoscopic hernia repair
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Stryker® Precision HD Camera System. 510(k) Summary

6) Comparison of Technological Characteristics with the Predicate Device

The Stryker Precision HD Camera System has the same technological characteristics and design as the predicate device except the following features:

a) A change in sterilization method – Uses steam sterilization method

b) A change in sensor technology within the camera head – Uses Charge-coupled device (CCD) sensor

c) Modification to the surgical mode selection on the CCU's interface touchscreen – It should be noted that the Stryker Precision HD Camera System does not include "Infrared" surgical mode selection on its interface touchscreen but it is sensitive to Infrared band. The proposed device maintains its Infrared capability by displaying the Infrared light as red image when used with Stryker Infravision Illuminator.

All other technological characteristics of both proposed and predicate devices are identical. Both devices consist of three main components: a camera head, a coupler, and a Camera Control Unit (CCU). Both devices receive optical image from a variety of scopes that are attached to the camera head via coupler and use image sensor to convert optical image into electronic signal. Both camera heads feature a button keypad for controlling of the device itself and the connected video peripheral devices. Both camera systems are sensitive to specific IR band.

The Camera Control Unit (CCU) of both devices contains software and acts as the control center of the device. The CCU of both devices contains a touchscreen with graphical user interface (GUI). The touchscreen menu of both devices has pre-defined surgical mode selections menu to allow users to optimize camera setting base on different surgical specialties.

The CCU of both devices is not intended to enter the sterile field, and should not be sterilized. The camera head and coupler of both devices are reusable devices and shall be sterilized prior to the first use and after every subsequent use.

7) Performance Data

The Precision HD Camera System was tested for performance in accordance with internal design specification and with the applicable performance standards.

Electrical safety and electromagnetic compatibility testing was performed in accordance to the standards listed below. Testing indicates that the proposed device conforms to these standards.

Stryker® Precision HD Camera System. 510(k) Summary

- *ANSI/AAMI ES60601-1:2005+A2 (R2012) + A1- Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- *IEC60601-1-2:2007 - Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests,*
- *IEC60601-2-18:2009 - Medical Electrical Equipment - Part 2-18: Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment*

Software was developed, tested, and verified per FDA guidance documents, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" and *IEC 62304:2006 - Medical Device Software – Software Life Cycle Processes.* The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could result in minor injury to the patient or operator.

The cleaning instructions provided in the labeling for reusable components were validated. Sterilization validation testing activities were performed in accordance with *ISO 14937:2009- Sterilization of Health Care Products — General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices.*

Bench performance testing was conducted to ensure that the device functioned as intended and met design specifications and acceptance criteria. Bench testing included video compatibility, DVI compliance, and system compatibility. Test results obtained verified the safety and effectiveness of the devices per design specifications and applicable standards.

8) Conclusion

Base on the indication of use, technological characteristic, performance testing and comparison to the predicate device, the Stryker Precision HD Camera System raises no new questions of safety and effectiveness as compared to the predicate device and is substantially equivalent to the predicate devices in terms of safety, efficacy and performance.