Stryker® 1488 HD Video Camera with Infrared Compatibility, Traditional 510(k)

DEC 16 2013

1. General Information

510(k) Sponsor	Stryker Endoscopy
Address	5900 Optical Court San Jose, CA 95138
FDA Registration Number	2936485
Correspondence Person	Lifei Liu Associate Regulatory Affairs Manager Stryker Endoscopy
Contact Information	Email: lifei.liu@stryker.com Phone: (408) 754-2315

2. Device Identification

Proposed Device:

Proprietary Name	Stryker 1488 HD Video Camera with Infrared Compatibility
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

Predicate Device:

Proprietary Name	Stryker Model 888 Video Camera
Common Name	3-Chip Video Camera
Premarket Notification	K983566
Classification Name	Laparoscope, General and Plastic Surgery
Regulation Number	21 CFR 876.1500
Product Code	GCJ
Regulatory Class	II

3. Device Description

The Stryker 1488 HD Video Camera with Infrared Compatibility (hereafter referred to as "proposed device") is used to view endoscopic surgical sites on video monitors. 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. The system is sensitive in the visible and infrared spectrum. The system consists of a camera control unit (CCU) and a camera head with an integral cable that connects to the CCU. The camera will provide a high quality image while remaining lightweight and easy to use. The system is intended to be used in orthopedic, laparoscopic, endoscopic, urological, microscopic, sinuscopic and plastic surgery and in dentistry, cardiology and wherever endoscopic procedures are deemed appropriate.

4. Indications for Use

The Stryker 1488 HD Video Camera with Infrared Compatibility 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 laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic

appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & 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 and examination of the evacuated cardiac chamber during performance of valve replacement. The users of the Stryker 1488 HD Video Camera with Infrared Compatibility are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

5. Intended Use

The Stryker 1488 HD Video Camera with Infrared Compatibility is an endoscopic camera system that is used to produce still and video images in the surgical field during surgical endoscopic procedures. The system is sensitive in the visible and infrared spectrum. The optical image is transferred from the surgical site to the camera head by a variety of rigid and flexible scopes which are attached to the camera head. The system consists of a camera control unit (CCU) and a camera head with an integral cable that connects to the CCU.

6. Technological Comparison

The proposed device has the same technological characteristics as the predicate device in the following areas:

- Operating principle
- Software architecture
- Electrical characteristics
- Mechanical characteristics
- Performance characteristics
- Energy source

7. Performance Testing

The proposed device was tested for performance in accordance with internal design specifications and with the applicable performance standards. Risk analysis was carried out, and subsequently design verification/validation activities and corresponding acceptance criteria were identified and performed in accordance with the risk analysis assessment.

Electrical safety and electromagnetic compatibility testing was performed in accordance to *IEC 60601-1:2005* and *IEC 60601-1-2:2007*, respectively. Testing indicates that the proposed device conforms to the aforementioned voluntary standards.

The software validation activities were performed in accordance with *IEC 62304:2006/AC: 2008* as well as the FDA Guidance documents, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*".

The sterilization validation testing activities were performed in accordance with *ISO 14937:2009* as described in *Section 11, Device Description.*

While no device specific guidance document from FDA was applicable to the proposed device, Stryker Endoscopy has chosen to comply with the following voluntary standards, which are recognized consensus standards for the product code **GCJ**:

Standard	Title of Standard
IEC 60601-2-18: 2009	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

ISO 8600-1: 2005	Optics and photonics -- Medical endoscopes and endotherapy devices -- Part 1: General requirements
ISO 8600-4: 1997	Optics and optical instruments -- Medical endoscopes and certain accessories -- Part 4: Determination of maximum width of insertion portion
ISO 8600-3: 1997 + Amendment 1	Optics and optical instruments - Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics
ISO 8600-5: 2005	Optics and photonics - Medical endoscopes and endotherapy devices - Part 5: Determination of optical resolution of rigid endoscopes with optics
ISO 8600-6: 2005	Optics and photonics - Medical endoscopes and endotherapy devices - Part 6: Vocabulary

8. Conclusion

The Stryker 1488 HD Video Camera with Infrared Compatibility has the following similarities as compared to its predicated device:

- Identical indications for use,
- Same Intended Use
- Same technological characteristics

In conclusion, the proposed device raises no new questions of safety and effectiveness as compared to its predicate device. Therefore, the proposed device is substantially equivalent to the predicate device Stryker Model 888 Video Camera.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Stryker Endoscopy
Lifei Liu
5900 Optical Court
San Jose, California 95138

December 16, 2013

Re: K132785
Trade/Device Name: Stryker 1488 HD Video Camera with Infrared Compatibility
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 18, 2013
Received: November 19, 2013

Dear Lifei Liu:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Joshua C. Nipper -S

Binita Ashar, MD, MBA, FACS
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Stryker® 1488 HD Video Camera with Infrared Compatibility, Traditional 510(k)

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K132785

Device Name: Stryker 1488 HD Video Camera with Infrared Compatibility

Indications for Use:

The Stryker 1488 HD Video Camera with Infrared Compatibility 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 laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopic appendectomy, laparoscopic pelvic lymph node dissection, laparoscopically assisted hysterectomy, laparoscopic & 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 and examination of the evacuated cardiac chamber during performance of valve replacement. The users of the Stryker 1488 HD Video Camera with Infrared Capability are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

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

(PLEASE DO NOT WRITE BELOW THIS LINE – COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.12.13 13:18:45
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(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number K132785