K082451

5900 Optical Court
San Jose, CA 95138
t: 408 754 2000 f: 408 754 2521

stryker®
Endoscopy

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

DEC 1 6 2008

Table 1

Proprietary Name:	Stryker Videoscope
Common and Usual Names:	Endoscopic Laparoscope, Gynecological Laparoscope, Videoscope
Classification Name:	Laparoscope, General & Plastic Surgery - CFR 21 § 876.1500, Laparoscope, Gynecological - CFR 21 § 884.1720

Product Description:

Device Description and Intended Use: The Stryker Videoscope is a video endoscope indicated for use in endoscopy and endoscopic surgery within the thoracic and abdominal cavities, including female reproductive organs.

Voluntary Safety and Performance Standards: The Stryker Videoscope will conform to the standards deemed applicable for this device. Please refer to section 5.1 for a list of standards that will be used.

Predicate Device

Table 2

Name	Manufacturer	510(k)
LAPARO THORACO VIDEOSCOPE XLTF-VAW	Olympus	K053382

Substantial Equivalence: The indications for use and most technological characteristics are the same for both devices. The few differences in technological characteristics are slight and do not raise new questions of safety and effectiveness, thus demonstrating that the Stryker Videoscope is at least as safe and effective as the Laparo Thoraco Videoscope XLTF – VAW that is currently legally marketed. Please see substantial equivalence table 4 for a detailed comparison.

1.0 INTRODUCTION

This 510(k) pre-market notification letter is submitted to notify the FDA of Stryker Endoscopy's intent to market the Stryker Videoscope. The Stryker Videoscope is a video endoscope indicated for use in endoscopy and endoscopic surgery within the thoracic and abdominal cavities, including female reproductive organs.

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2.0 DEVICE SPONSOR:

Stryker Endoscopy is the sponsor of this pre-market notification. Stryker Endoscopy has an established history of manufacturing and marketing medical products for endoscopic surgery.

Table 3

Sponsor of 510(k):	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138 FDA Registration # 2936485
Owner:	Stryker Corporation 2725 Fairfield Road Kalamazoo, MI 49002 FDA Registration # 1811755
Manufacturer of Videoscope	Henke-Sass,Wolf, GMBH Keltenstrasse 1 Tuttlingen, Germany D-78532 FDA Registration # 8010418
Manufacturer of Camera Control Unit (CCU)	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138 FDA Registration # 2936485
Correspondence Regarding this 510(k):	Desiree Crisolo Sr. Regulatory Representative Stryker Endoscopy 5900 Optical Ct. San Jose, CA 95138 Phone: 408-754-2784 Fax: 408-754-2521 Email: Desiree.Crisolo@Stryker.com

3.0 DEVICE IDENTIFICATION

3.1 Proposed Device Name

Table 4

Proprietary Name:	Stryker Videoscope
Common and Usual Name:	Endoscopic Laparoscope, Gynecological Laparoscope , Videoscope

3.2 Predicate Device Name

Table 5

Name	Manufacturer	510(k)
LAPARO THORACO VIDEOSCOPE XLTF-VAW	Olympus	K053382

4.0 CLASSIFICATION AND PRODUCT CODE

Table 6

Classification Name	Product Code	Product Class	Regulation Number
Laparoscope, General and Plastic Surgery	GCJ	II	876.1500
Laparoscope, Gynecologic	HET	II	884.1720

4.1. Advisory Committee General & Plastic Surgery
Obstetrics/Gynecology

5.0 SECTION 514 SPECIAL CONTROLS

No performance standards or special controls have been established under section 514 of the Federal Food, Drug, and Cosmetic Act.

However, Stryker Endoscopy has chosen to comply with the following voluntary standards:

5.1. Voluntary Standards

Table 7

Standard	Title of Standard
EN 550: 1994	Sterilization of Medical Devices: Validation and routine Control of Ethylene Oxide Sterilization
ISO 14971:2007	Medical Devices- Application of risk management to medical devices.
ISO 10993-1:2003	Biological evaluation of medical devices- Part 1: Evaluation and testing.
ISO 10993-5:1999	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

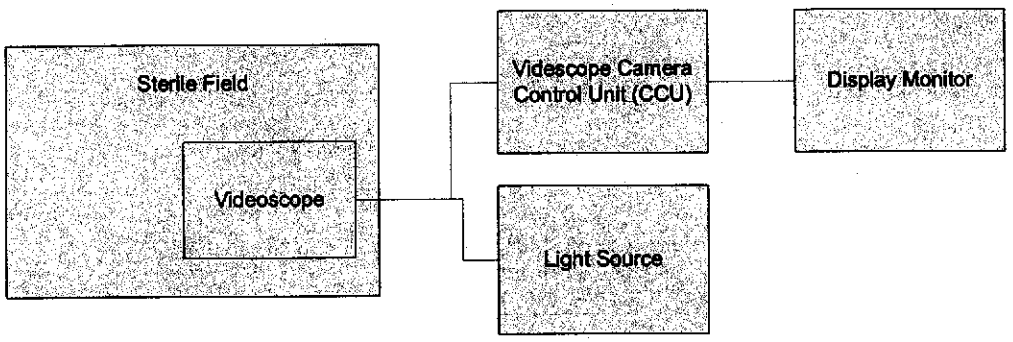
ISO 10993-7:1995	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2002	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
ISO 10993-11:2006	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices (G 95-1)	Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"
IEC 60601-1:2005	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-1:2000	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2:2001 + A1:2004	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: ~~Safety Requirements for Medical Electrical Systems~~ EMC
IEC 60601-1-4:2000 +A1:1999	Medical Electrical Equipment – Part 1-4: General Requirements for Safety Collateral Standard: Programmable Medical Devices
IEC 60601-2-18:1996	Medical Electrical Equipment – Part 2: Particular Requirements for the safety of endoscopic equipment
ISO 8600-1:2005	Optics and Photonics – Medical Endoscopes and Endotherapy Devices Part 1: General Requirements
ISO 8600-3:1997	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 8600-4	Optics and optical instruments – Medical endoscopes and endoscopic accessories – Part 4: Determination of maximum width of insertion portion

6.0 DEVICE DESCRIPTION

6.1. Intended Use: The Stryker Videoscope is a video endoscope indicated for use in endoscopic surgery within the thoracic and abdominal cavities, including female reproductive organs.

6.2. System Description and Diagrams

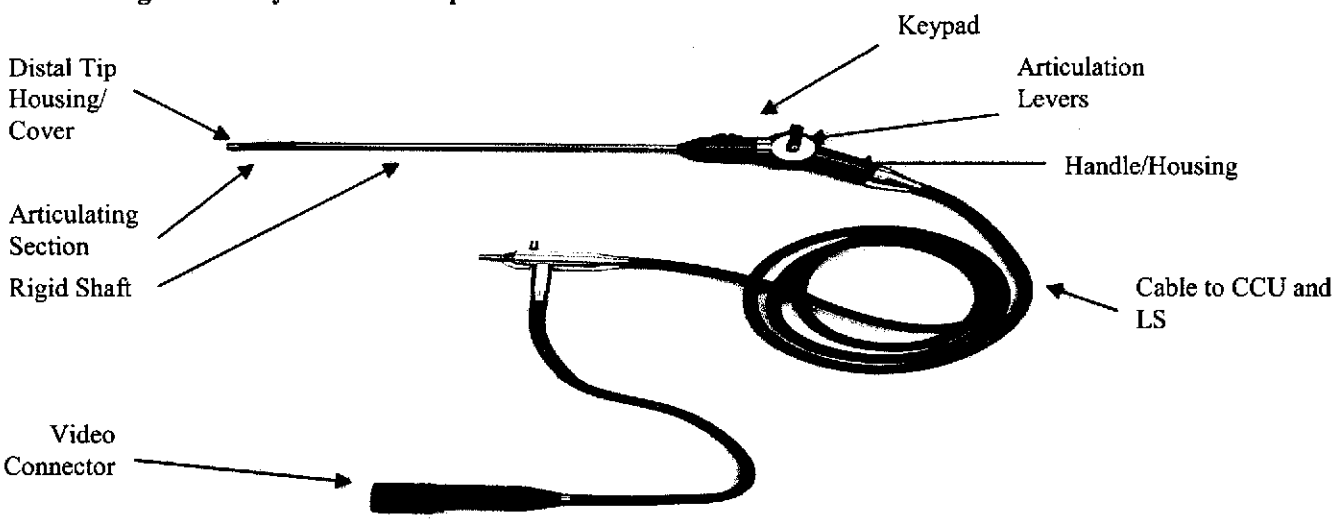
Figure 1: Stryker Videoscope System Block Diagram



6.2.1. Stryker Videoscope

The Stryker Videoscope is intended to illuminate and allow observation of body cavities relating to general endoscopic, laparoscopic and gynecological surgeries. Traditionally, surgeons would need multiple scopes with varying direction of view angles (such as 0°, 30°, and 45°) to have a wide range of view. The Stryker Videoscope can provide varying angles all in one scope through a distal articulating section that changes the direction of view between 0° and 110° (±10°) from the axis of the scope. The Videoscope will have a working length of 330mm, with an outer diameter of 10mm.

Figure 2: Stryker Videoscope



6.2.2. Materials

Table 8: Patient Contacting Materials

Component	Device Component	Material
Videoscope	Distal Tip Housing/Rigid Shaft/ Articulation Levers	304 Stainless Steel
	Distal Tip Cover	Glass
	Articulating Section	Viton
	Housing	6061 – T6 Aluminum Anodized
	Keypad	Silicone Rubber
	Cable	Silicone Rubber

6.3. Safety and Performance Testing

6.3.1. Mechanics/Articulating mechanism and controls: The Stryker Videoscope has an articulating distal tip to allow the user to view the surgical area. The articulating section is made up of several links that are attached to four guide wires. These guide wires run from the distal tip up into the handle where the control levers are located. The external control handles, when moved, drive the internal articulating mechanism to push and pull the bending section in four directions and operates similarly to a pulley system. A mechanical reliability test will be conducted to ensure optimal performance and reliability.

6.3.2. Biocompatibility
All patient contacting materials are validated for biocompatibility in accordance with the requirements of ISO 10993-1:2003 and FDA Blue Book Memorandum #G95-1. Additionally, patient-contacting and user-contacting materials do not contain natural rubber or latex. Refer to Section 6.2.2 or Table 3 for patient contacting materials.

6.3.3. Sterilization: The Stryker Videoscope will be a reusable device. As such, it will undergo Sterility Assurance Validation testing to ensure it is able to be sterilized to a SAL $\leq 10^{-6}$. The two methods of sterilization that will be available to the users are Sterrad and ETO. ETO Residuals will be tested according to ISO10993-7.

7.0 SUBSTANTIAL EQUIVALENCE COMPARISON

The Stryker Videoscope described in this 510(k) notification is substantially equivalent to the currently marketed predicate device; the Olympus Laparo-Thoraco Videoscope XLTF-VAW. The fundamental technology and intended use is similar for both the Stryker Videoscope and Olympus Laparo Thoraco Videscope XLTF-VAW. In the following sections, the proposed device's characteristics are compared with the predicate device and the differences with respect to their impact on safety and effectiveness are discussed.

Table 9: Substantial Equivalence Table

	Proposed Device Stryker Videoscope	**Predicate Device** Olympus Laparo Thoraco Videoscope XLTF-VAW (K053382)	**Same or Different**	**Equivalence**
Characteristics				
Intended Use	The Stryker Videoscope is a video endoscope intended for use in endoscopy and endoscopic surgery within the thoracic and abdominal cavities, including female reproductive organs.	LAPARO-THORACO VIDEOSCOPE XLTF-VAW is designed for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.	Same	Equivalent
Field of View(FOV), (Degree)	75° +/- 5°	90°	Different	Equivalent
Direction of View (degree)	0° Forward Viewing	0° Forward Viewing	Same	Equivalent
Outer Diameter of Distal End	10mm	10.5mm	Different	Equivalent
Bending Section Angulations (UP/DOWN/ LEFT/RIGHT), (degree)	110°/110°/110°/110°, ± 10	100°/100°/60°/60°	Different	Equivalent
Working Length (mm)	330mm	330mm	Same	Equivalent
Inner Working Channel	None	Provided	Different	Equivalent

7.1. DISCUSSION OF DIFFERENCES

7.1.1. Outer Diameter: The diameter of the Stryker Videoscope is .5mm smaller than the Olympus Laparo Thoraco Videoscope XLTF-VAW. Laparoscopes generally come in 5mm and 10 – 11mm. Both the Stryker and Olympus Videoscopes fall within the 10-11mm range. The slight difference in diameter will not significantly affect the optical image or the incision created when used in surgery.

7.1.2. Bending Section Angulations/FOV: The Stryker Videoscope will have a bending articulation of 110° (±10°) up, down, left and right with a field of view (FOV) of 75 degrees. The Olympus Laparo Thoraco Videoscope XLTF-VAW has a bending articulation of 100° up and down, 60° left and right with a FOV of 90 degrees. The bending section angulations allow the user to vary the direction of view, while the FOV dictates how much the user sees within the image. In general, as the FOV gets bigger, the image quality tends to get reduced. By keeping a smaller FOV, the Stryker Videoscope may maintain a greater degree of image quality. The device will have the ability to articulate at 110° all around, so that although the FOV is smaller than the Olympus Videoscope, the direction of view can be varied 50° more to the left and right. The surgeon will have the convenience of articulating 110° (±10°) all around, allowing more flexibility through articulation while minimizing the movement of the scope handle.

7.1.3. Inner Working Channel: An inner working channel will not be provided with the Stryker Videoscope. The predicate device uses the inner working channel to perform insufflation and irrigation, both of which are not indicated in the Stryker Videoscope.

8.0 CONCLUSION

As demonstrated through comparisons between the predicate device Olympus Laparo Thoraco Videoscope XLTF-VAW and the proposed, the Stryker Videoscope, no significant differences exist in the indications for use, surgical procedures, constructions, performance specifications and labeling of these devices. As there are no significant differences, there are no new questions raised regarding safety and effectiveness. Therefore, the Stryker Videoscope is considered, in terms of safety and effectiveness, substantially equivalent to the currently marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Desiree Mae Crisolo
Sr. Regulatory Representative
Stryker® Endoscopy
5900 Optical Court
SAN JOSE CA 95138

DEC 1 6 2008

Re: K082451
Trade/Device Name: Stryker Videoscope
Regulation Number: 21 CFR §884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Codes: HET and GCJ
Dated: November 25, 2008
Received: November 28, 2008

Dear Ms. Crisolo:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

Device Name: Stryker Videoscope

510(k) Number: K082451

The Stryker Videoscope is a video endoscope indicated for use in endoscopy and endoscopic surgery within the thoracic and abdominal cavities, including female reproductive organs.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082451