K081995

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Endoscopy

510(k) SUMMARY

OCT - 2 2008

Device Sponsor:

Sponsor and Manufacturer:	Stryker Endoscopy 5900 Optical Court San Jose, CA 95138 FDA Registration # 2936485
Correspondence Regarding this 510(k):	Monica Barrett Sr. Regulatory Affairs Representative Stryker Endoscopy 5900 Optical Court San Jose, CA t: 408-754-2078 f: 408-754-2521 monica.barrett@stryker.com

Device Name:

Proprietary Name:	Stryker Vision Elect WHDTV
Common and Usual Name:	television, monitor, screen, display, flat panel, flat screen
Classification Name:	General & Plastic Surgery Devices Panel Surgical camera and accessories Class I, 21 CFR 878.4160 Product Code FWF

Predicate Device:

The VE WHDTV is substantially equivalent in terms of safety and efficacy to currently available viewing systems on the market including the Stryker Vision Elect HDTV.

Device Description:

The Vision Elect WHDTV (VE WHDTV) is a high-definition, widescreen LCD surgical display with a maximum resolution of WUXGA (1920 × 1200 at 60 Hz). The VE WHDTV supports various video inputs, including digital RGB, analog RGB, serial digital interface (SDI), component video (YPbPr/RGB), S-video, and C-video.

The VE WHDTV features an optional optical module accessory, which allows it to receive a high-definition video signal over fiber optic cables. It also features an optional wireless transmitter, which allows it to receive a high-definition video signal over a radio-frequency link.

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The VE WHDTV and its accessories will meet the necessary electrical safety (IEC 60601-1), EMC (IEC 60601-1-2) and radio frequency device (47 CFR part 15) requirements.

Intended Use:

The Stryker Vision Elect WHDTV (VE WHDTV) is intended for video display during surgical procedures including arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery), thorascopy, endoscopy (general, gastroenterological and ENT surgery) and general surgery. The VE WHDTV is a non-sterile reusable device not intended for use in the sterile field. The VE WHDTV is intended for use by qualified physicians having complete knowledge of these surgical procedures.

Predicate Device:

The Stryker Vision Elect WHDTV is substantially equivalent in terms of safety and efficacy to the currently marketed devices including the Stryker Vision Elect HDTV.

Name: Stryker Vision Elect HDTV
Manufacturer: Stryker Endoscopy
510(k) #: N/A, Class I, 21 CFR 878.4160 Surgical camera and accessories

Substantial Equivalence:

When compared to the predicated device listed above, the Stryker VE WHDTV has the same intended use and the technological differences do not raise new questions of safety and efficacy. Therefore, the Stryker VE WHDTV is substantially equivalent to the predicate marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Endoscopy
% Ms. Monica Barrett
Senior Regulatory Affairs Representative
5900 Optical Court
San Jose, California 95138

OCT - 2 2008

Re: K081995
Trade/Device Name: Stryker Vision Elect Wireless High Definition Television (Stryker VE WHDTV)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories.
Regulatory Class: II
Product Code: GCJ
Dated: September 11, 2008
Received: September 11, 2008

Dear Ms. Barrett:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 Biometric's (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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081995

INDICATIONS FOR USE STATEMENT

Device Name: Stryker Vision Elect Wireless High Definition Television (Stryker VE WHDTV).

510(k) Number if known: K081995

The Stryker Vision Elect WHDTV (VE WHDTV) is intended for video display during surgical procedures including arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery), thorascopy, endoscopy (general, gastroenterological and ENT surgery) and general surgery. The VE WHDTV is a non-sterile reusable device not intended for use in the sterile field. The VE WHDTV is intended for use by qualified physicians having complete knowledge of these surgical procedures.

Contraindications:

There are no contraindications for this product.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081995