



Food and Drug Administration  
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August 20, 2015

Stryker Endoscopy  
Golnaz Moeini  
Sr. Regulatory Affairs Analyst  
5900 Optical Ct  
San Jose, CA 95138

Re: K151243  
Trade/Device Name: Stryker Infrared Illumination System (IRIS) [AIM Light Source and Ureteral Kit]  
Regulation Number: 21 CFR 876.4020  
Regulation Name: Fiberoptic Light Ureteral Catheter  
Regulatory Class: II  
Product Code: FCS, FCW  
Dated: June 26, 2015  
Received: June 29, 2015

Dear Golnaz Moeini,

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,

**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151243

Device Name

Stryker® Infrared Illuminating System (IRIS)[AIM Light Source and IRIS Ureteral Kit]

Indications for Use (Describe)

The Stryker AIM Light Source is intended to trans-illuminate anatomical structures during open or laparoscopic surgical procedures.

The Stryker® AIM Light Source and SafeLight Cable are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The Stryker® AIM Light Source and SafeLight Cable enable surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the Stryker® AIM Light Source and SafeLight Cable are intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization.

The Stryker IRIS Ureteral Kit when used with compatible Stryker Infrared sources is intended to trans-illuminate the ureter during surgical procedures. The catheter accepts up to 0.038” guide wire. The kit can be used for either open surgical or laparoscopic procedures.

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## Section 5. 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	Golnaz Moeini Sr. Regulatory Affairs Analyst Stryker Endoscopy
Contact Information	Email: <a href="mailto:golnaz.moeini@stryker.com">golnaz.moeini@stryker.com</a> Phone: 408-754-2755
Date Prepared	6/24/2015

### 2. Proposed Device

Proposed Device:

Proprietary Name	<i>Stryker® Infrared Illuminating System (IRIS)[ Consisting of AIM Light Source and IRIS Ureteral Kit ]</i>
Common Name	<i>Light Source, Illuminator</i>
Classification Name	Fiberoptic light ureteral catheter, Light Source, Fiberoptic, Routine
Regulation Number	21 CFR 876.4020, 21 CFR 876.1500
Product Code	FCS, FCW
Regulatory Class	II

### 3. Predicate Device

Primary Predicate Device:

Proprietary Name	<i>Stryker Ureteral Illumination System IV [Consisting of Infravision Illuminator and Universal Ureteral Kit ]</i>
Premarket Notification	K061548
Classification Name	Fiber Optic Light Ureteral Catheter
Regulation Number	21 CFR 876.4020
Product Code	FCS
Regulatory Class	II

Secondary Predicate Device:

Proprietary Name	<i>Stryker® Infrared Fluorescence (IRF) Imaging System</i>
Premarket Notification	K142310
Classification Name	Confocal Optical Imaging
Regulation Number	21 CFR 876.1500
Product Code	OWN
Regulatory Class	II

## 4. Device Description

The *Stryker® Infrared Illuminating System (IRIS)* is used to trans-illuminate the ureter during laparoscopic or open surgical procedures. Trans-illumination is intended to help the surgeon identify the ureter(s) during open or laparoscopic surgical procedure of lower abdomen or pelvic areas. The *Stryker® Infrared Illuminating System (IRIS)* consists of the following main components (herein referred to as ‘proposed devices’):

- A light source console.
- A Ureteral Kit that consists of two *catheters*, one fiber assembly containing two *catheters*, one fiber assembly containing two *light emitting fibers*, one *catheter dispenser*, one *light emitting fiber dispenser*, two *luer connectors*, and two *drape clips*.

## 5. Indications for Use

### Indications for Use for Light Source

The *Stryker AIM Light Source* is intended to trans-illuminate the ureter during open or laparoscopic surgical procedures.

The *Stryker® AIM Light Source and SafeLight Cable* are indicated for use to provide real-time endoscopic visible and near-infrared fluorescence imaging. The *Stryker® AIM Light Source and SafeLight Cable* enable surgeons to perform minimally invasive surgery using standard endoscope visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, and at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging.

Fluorescence imaging of biliary ducts with the *Stryker® AIM Light Source and SafeLight Cable* are intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The devices are not intended for standalone use for biliary duct visualization.

### Indications for Use for Ureteral Kit

The *Stryker IRIS Ureteral Kit* when used with compatible Stryker Infrared sources is intended to trans-illuminate the ureter during surgical procedures. The catheter accepts up to 0.038” guide wire. The kit can be used for either open surgical or laparoscopic procedures.

## 6. Comparison of Technological Characteristics with the Predicate Device

As noted above, the *Stryker® Infrared Illuminating System (IRIS)* is equivalent to the following cleared device in terms of its indications for use, design technology and performance specification:

With respect to the indications for use of the light source console, the proposed Stryker light source console is substantially equivalent to *Stryker Ureteral Illumination System IV (K061548)* and *Stryker® Infrared Fluorescence (IRF) Imaging System (K142310)*.

With respect to the design technology and performance specifications, the Stryker proposed light source console is substantially equivalent to *Stryker Ureteral Illumination System IV (K061548)*.

With respect to the Ureteral Kit, the proposed Stryker Ureteral Kit is substantially equivalent to *Stryker Ureteral Illumination System IV (K061548)* since they are both the same in design and indication for use with very minor modification to the proposed device to improve usability of the light fibers.

## 7. Performance Data

Safety and performance of the *Stryker® Infrared Illuminating System (IRIS)* has been evaluated and verified in accordance with design specifications and applicable performance standards through biocompatibility assessment, electrical safety and EMC testing, software validation, bench testing and animal testing. The following performance testing were conducted and are summarized in this submission:

- Biocompatibility was assessed in accordance to *ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process and related collateral standards for patient contacting materials*.
- The proposed *Ureteral Kit* is provided sterile. Ethylene oxide sterilization was verified per *ISO 11135:2014: Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of sterilization process for medical devices* (see *Section 14, Sterilization and Shelf Life*).
- Electrical Safety and electromagnetic compatibility testing was performed in accordance to *IEC 60601-1:2005+A1:2012 - Medical electrical equipment- Part 1: General requirements for basic safety and essential performance* and *IEC 60601-1-2:2007- Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral Standard: Electromagnetic disturbances – Requirement and tests*, 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- Medical device software – Software life cycle processes* as well as the FDA Guidance documents, “*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*”.
- Bench performance testing was conducted to ensure that the devices functioned as intended and met design specifications and acceptance criteria. Test results obtained verified the safety and effectiveness of the devices per design specifications and applicable standards.
- Cadaver testing validated the ureteral trans-illumination capability of the *Stryker® Infrared Illuminating System (IRIS)*.

## 8. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the *Stryker*<sup>®</sup> *Infrared Illuminating System (IRIS)* raises no new questions of safety and effectiveness and is substantially equivalent to the predicate devices in terms of safety, efficacy and performance.