



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 15, 2015

Santa Barbara Imaging Systems
James Candy
Director
340 Storke Road, Suite 101
Goleta, California 93117

Re: K152513
Trade/Device Name: 8X-10-XXXX Camera System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 30, 2015
Received: November 5, 2015

Dear James Candy:

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,


Herbert P. Lerner -S

for 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)

K152513

Device Name

8X-10-XXXX Camera System

Indications for Use (Describe)

The 8X-10-XXXX Camera System is indicated for use in diagnostic and operative endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening. The 8X-10-XXXX Camera System is indicated for use with a compatible 8X-10-XXXX Camera Head and other accessory devices including an endoscope, optical coupler, and light cable.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Santa Barbara Imaging Systems, Incorporated is hereby submitting this 510(k) summary.

Submitter [510(k) owner]

Santa Barbara Imaging Systems, Incorporated.

340 Storke Road, Suite 101

Goleta, CA 93117

Company Contact

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Submitted Device Information

Trade Name: 8X-10-XXXX Camera System
Common Name: Endoscope And Accessories
Classification Name: Laparoscope, General & Plastic Surgery

Classification Information

Classification: Class II
Classification Regulation: 21 CFR 876.1500
Classification Product Code: GCJ

Legally Marketed Predicate Devices

The 8X-10-XXXX Camera System manufactured by Santa Barbara Imaging Systems (SBIS) is substantially equivalent to the following device currently in commercial use:

Device:	OVS I Video System
Manufacturer:	Olive Medical Corporation
Address:	2302 S Presidents Drive, Suite D, Salt Lake City, Utah, 84120
510(k) number:	K123359

Submitted Device Description

The 8X-10-XXXX Camera System is a high-definition camera used to capture still and video images of endoscopic or general surgical applications. The system also incorporates an optional internal light source featuring a Turret Light Guide Adapter which accepts various light guides. The 8X-10-XXXX Camera System consists of a console and a compatible 8X-10-XXXX camera head.

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Intended Use

The 8X-10-XXXX Camera System, with optional integrated LED light source and image/video capture, is to be used when performing a variety of minimally invasive surgical procedures and for general medical visualization and video archive applications. The 8X-10-XXXX Camera System incorporates a remote camera head which displays the image, as presented through an endoscope, microscope, integrated or coupled optics, onto a viewing monitor. Displayed images and videos may be captured and stored internally or transferred or transmitted via a variety of means, controlled through the device's integrated touch panel or an optional secondary remote control mobile device.

The 8X-10-XXXX is intended to be used in a controlled operating room environment with compatible devices by qualified medical personnel. The camera heads are provided non-sterile. The endoscopic camera head may be sterilized by steam autoclave or other prescribed sterilization methods. The system has a 3 year expected service life.

Indications for Use:

The 8X-10-XXXX Camera System is indicated for use in diagnostic and operative endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening. The 8X-10-XXXX Camera System is indicated for use with a compatible 8X-10-XXXX Camera Head and other accessory devices including an endoscope, optical coupler, and light cable.

Substantial Equivalence

The 8X-10-XXXX Camera System is substantially equivalent to the predicate device. The 8X-10-XXXX Camera System does not raise any new questions of safety or effectiveness.

The following table summarizes the characteristics of the 8X-10-XXXX Camera System (SBIS Subject Device) and the OVS1 Video System (Predicate Device) that were evaluated.

SBIS 8X-10-XXXX Camera System	OVS I Video System (K123359)	Comparison
Device Description	Device Description	Substantially Equivalent
Indications for Use	Indications for Use	Same
Intended Use	Intended Use	Substantially Equivalent
Skill Level Required for User	Skill Level Required for User	Same
Configuration	Configuration	Same
Primary Device Functions	Primary Device Functions	Substantially Equivalent
Primary Device Controls (via integrated Front Panel Display or Camera Head Buttons)	Primary Device Controls (via integrated Front Panel Display or Camera Head Buttons)	Substantially Equivalent
Secondary Device Functions	Secondary Device Functions	Substantially Equivalent
Compatible Equipment/Accessories	Compatible Equipment/Accessories	Substantially Equivalent
Technology	Technology	Substantially Equivalent
Performance	Performance	Substantially Equivalent
Material	Material	Substantially Equivalent
Energy Source	Energy Source	Same
How Supplied	How Supplied	Same
Safety Standard	Safety Standard	Same
Biocompatibility	Biocompatibility	Same
Sterility	Sterility	Same

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Non-Clinical Testing:

The 8X-10-XXXX Camera System demonstrates substantial equivalence in safety by tested compliance with:

- IEC 60601 -1: Medical electrical equipment -Part 1: General requirements for basic safety and essential performance; and
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

Bench testing of performance specifications were completed and demonstrate that the device met all requirements. Bench comparison testing between the predicate device and the 8X-10-XXXX Camera System demonstrated that the devices are substantially equivalent.

Clinical Testing:

No comparison of clinical performance data was used for demonstration of substantial equivalence.

Equivalence Standards Compliance

The 8X-10-XXXX Camera System has been tested and found to comply with the relevant international Medical Device Standards for Safety.

- IEC 60601-1 Medical Electrical Equipment, General Standards
- IEC 60601-1-2 Medical Electrical Equipment, Requirements for Electromagnetic Compatibility
- IEC 60601-2-18 Medical Electrical Equipment, Particular Requirements for Endoscopic Equipment