K081698

JUL 30 2008

510(k) Summary

Date prepared May 30, 2008

510(k) Owner
Image Stream Medical, Inc.
One Monarch Drive
Littleton, MA
01460

Phone: (978) 486-8494
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Contact Mona Pinette, Chief Operating Officer

Trade name MainStream® OR Surgical Light Control

Common name Surgical Light Accessory

Classification name

Classification Name:	Light, Surgical, Accessories
Classification Panel:	General & Plastic Surgery
CFR Section:	21 CFR 878.4580
Class:	2
Product Code:	FTA

Predicate device SCB/Steris OR-Light Interface Box, which was cleared to market in 510(k) # K051505.

Device description The MainStream® OR Surgical Light Control (MSLC) is an optional function in the MainStream ® OR, which is an integrated operating room system for configurable communication of images from sources to displays within the operating room, for management of audio systems, and for control of devices such as room lights.

The MSLC function allows control of surgical lights from the MainStream® OR touch panel user interface.

Intended use

MainStream® OR Surgical Light Control (MSLC) allows the control of surgical lights from the Mainstream® OR touch panel user interface. It does not perform calculations. It displays surgical light status on the MainStream® OR display and allows control of the surgical lights. The safety features and controls of the surgical light system take precedence over the MainStream® OR surgical light control.

MSLC is an optional function in the MainStream® OR integrated operating room system. (The MainStream® OR system includes a touch panel user interface for quick routing of surgical images to displays within the operating room and for convenient control of room video cameras, surgical cameras, ambient lighting, and surgical lights. MainStream® OR also includes an audio management system and a single point of entry for querying surgical charts and image archives.)

Comparison to the predicate device

	MSLC	SCB/Steris OR-Light Interface Box
Function	Control of surgical lights from a convenient integrated operating room system.	
Primary control of surgical lights	The surgical light controls from the surgical light system manufacturer take precedence over the integrated system.	
Calculations performed	None	
Primary purpose of integrated operating room system.	MainStream® OR is a primarily medical video image routing and communication system, which also controls functions such as ambient lighting.	The SCB (Storz Communication Bus) system is the backbone for an integrated operating room system that additionally interfaces with endoscopes.
Sterile field	No components are used in the sterile field.	

Conclusion

The MSLC is substantially equivalent to the SCB/Steris OR-Light Interface Box, which was cleared to market in 510(k) K051505.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Image Stream Medical, Inc.
% Chas Burr Q/R Services, Inc.
Mr. Chas Burr
11 Mystic Avenue
Winchester, Massachusetts 01890-2920

JUL 30 2008

Re: K081698
Trade/Device Name: MainStream® OR Surgical Light Control
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FTA
Dated: May 30, 2008
Received: June 17, 2008

Dear Mr. Burr:

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

Indications for Use

510(k) Number (if known): K081698

Device Name: MainStream® OR Surgical Light Control

Indications for Use:

MainStream® OR Surgical Light Control (MSLC) allows the control of surgical lights from the Mainstream® OR touch panel user interface. It does not perform calculations. It displays surgical light status on the MainStream® OR display and allows control of the surgical lights. The safety features and controls of the surgical light system take precedence over the MainStream® OR surgical light control.

MSLC is an optional function in the MainStream® OR integrated operating room system. (The MainStream® OR system includes a touch panel user interface for quick routing of surgical images to displays within the operating room and for convenient control of room video cameras, surgical cameras, ambient lighting, and surgical lights. MainStream® OR also includes an audio management system and a single point of entry for querying surgical charts and image archives.)

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 General, Restorative,
and Neurological Devices

510(k) Number K081698