Attachment 3

510 (k) Summary

K102791

Date prepared	September 22, 2010
510(k) Owner	Image Stream Medical, Inc. One Monarch Drive Littleton, MA 01460 NOV 2 3 2010 Phone: (978) 486-8494 Fax: (978) 428-2694
Contact	Beth Cyr, Director of Quality Assurance
Trade name	EasySuite™ 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	MainStream™ OR Surgical Light Control (MSLC), which was cleared to market in 510(k) # K081698.
Device description	The EasySuite™ Surgical Light Control (ESLC) is an optional function in the EasySuite™, 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 ESLC function allows control of surgical lights from the EasySuite™ touch panel user interface.

Intended use

EasySuite™ Surgical Light Control (ESLC) allows the control of surgical lighting during a surgical procedure from the EasySuite™ touch panel user interface.

ESLC Description

ESLC is an optional function in the EasySuite™ integrated operating room system. (The EasySuite™ 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. EasySuite™ 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	ESLC
Control Platform	Crestron	Microsoft Windows Standard Embedded
Function	Control of surgical lights from a convenient integrated operating room system. Control is defined by setting the light intensity or the lights on or off.	
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.	The system is primarily medical video image routing and communication system, which also controls functions such as ambient lighting.	
Sterile field	No components are used in the sterile field.	

Non-Clinical Tests The EasySuite™ Surgical Light Control (ESLC) is a software application. Verification and validation testing was performed by Image Stream personnel. The verification and validation confirmed that the ESLC application meets specified requirements.

Conclusion The ESLC is substantially equivalent to the MainStreamTM OR Surgical Light Control (MSLC), which was cleared to market in 510(k) # K081698.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Image Stream Medical, Inc.
% Ms. Beth Cyr
Director of Quality Assurance
One Monarch Drive
Littleton, Massachusetts 01460

NOV 2 3 2010

Re: K102791
Trade/Device Name: EasySuite™ Surgical Light Control
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FTA
Dated: November 09, 2010
Received: November 10, 2010

Dear Ms. Cyr:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachments

Attachment 1

NOV 2 3 2010

Indications for Use Statement

510(k) Number (if known) # K102791

Device Name EasySuite™ Surgical Light Control

Indications for Use EasySuite™ Surgical Light Control (ESLC) allows the control of surgical lighting during a surgical procedure from the EasySuite™ touch panel user interface.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

Mark R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102791