K071180

SECTION 5. 510(K) SUMMARY

JUN 20 2007

Submission Correspondent:	Keystone Regulatory Services, LLC 342 E. Main Street Suite 211 Leola, PA 17557 USA Phone: 717-656-9656 Fax: 717-656-3434 Email: bill.mclain@keystoneregulatory.com Contact: William G. McLain President and Principal Consultant
Submission Sponsor:	Engineered Medical Solutions Co. LLC 85 Industrial Drive Phillipsburg NJ, 08865 USA Phone: 908-329-9117 Fax: 908-454-5394 Email: pchurch@bihler.com Contact: Phil Church QA Manager
Date summary prepared:	March 3, 2007
Device trade name:	Scintillant Surgical Light
Device common name:	Surgical light, Surgical illuminator
Device classification name:	FTD, 21 CFR Part 878.4580, Surgical Lamp.
Legally marketed devices to which the device is substantially equivalent:	AtriCure Dissector, K041681 Light Port Surgical Illuminator, K041621 VersaLight Multi-Function Surgical Illuminator, Class I LightMat Surgical Illuminator, Class I
Description of the device:	The Scintillant Surgical Light is an untethered, self-contained medical lighting device that allows illumination inside the surgical field. The light can be hand-held and is provided with accessories which allow it to be attached to almost any surgical tool or instrument. The light is provided sterile and is battery powered. The light consists of a light-emitting diode (LED) mounted on the end of a flexible wand. A single button turns the light on and off. A battery and circuit board are contained in the device handle.

K071180

Intended use of the device:	The Scintillant light is intended to provide localized illumination of surgical sites.
Technological characteristics:	The technological characteristics between the predicate and proposed device are similar. Both are sterile, hand-held, battery powered surgical field illuminating devices and regarding the lighting function have the same overall intended use and indications for use.
Conclusions:	Other than the Atricure dissector being labeled as a cutting instrument, there are no significant differences between the Atricure Dissector and the Scintillant Surgical Light. Therefore, the proposed device does not raise any questions regarding safety and effectiveness. The Scintillant Surgical Light, as designed, is as safe and effective as the predicate device. Comparisons have been made to a legally marketed predicate device, and the device is determined to be substantially equivalent to the references predicate device currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Engineered Medical Solutions Co. LLC
c/o Patricia L. Murphy
Kema Quality B.V.
4377 County Line Road
Chalfont, PA 18914

Re: K071180
Trade/Device Name: Scintillant Surgical Light
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FTD
Dated: June 4, 2007
Received: June 5, 2007

JUN 2 0 2007

Dear Ms. Murphy:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number: K071180

Device Name: Scintillant Surgical Light

Indications for Use: The Scintillant Surgical Light is intended to provide localized illumination of surgical sites.

Prescription Use X AND/OR Over-The-Counter Use -
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K071180