DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 29, 2014

Litex Manufacturing Incorporated
Mr. Mike Hoftman
Advanced Medical Innovations
8741 Shirley Avenue
Northridge, California 91324

Re: K142386
Trade/Device Name: Light Handle Adapters
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FTA
Dated: August 18, 2014
Received: August 27, 2014

Dear Mr. Hoftman:

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" (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 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,

Binita S. Ashar -S
2014.09.29 15:15:54 -04'00'

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Light Handle Adapters

Indications for Use *(Describe)*
The Light Handle Adapters are permanent replacements to the original OEM handle provided by the light manufacturer in the event that the customer wishes to use a disposable light handle cover. This will eliminate the cleaning and re-sterilizing of the original OEM reusable light handle. The customer will need to replace the original OEM handle, with the light handle adapter that Litex Manufacturing, Inc. will provide the facility, through the light companies and other distributors.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Exhibit #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is:

1. **Submitters Identification:**

Contact Person: Noel Gharibian

Address: Litex Manufacturing, Inc.
1501 Sunshine Drive,
Glendale, CA 91208

Tel: 818-547-6777

Fax: 818-547-6777

Date Prepared: July 31, 2014

2. **Name of the Device:** Light Handle Adapters
3. **Common Name:** Light, Surgical, Accessories

Regulation: 878.4580

Product Code: FTA

4. **Predicate Device Information and Comparison:**

Device Description	Predicate Device	510(k) Number	Comparison
Litex Manufacturing, Inc. Light Handle Adapters	American Medical MFG., Inc. Plastic Disposable Surgical Light Handle Cover & Adapters.	**K915068**	The subject device is basically identical to the predicate device with respect to technological characteristics and function of the adapters.

5. **Device Description:**

   The Litex Manufacturing, Inc. Light Handle Adapter is a permanent replacement for the light manufacture's OEM reusable handle and it is designed to be permanently attached to the surgical light.

6. **Intended and Indication for Use:**

   The Light Handle Adapters are permanent replacements to the original OEM handle provided by the light manufacturer in the event that the customer wishes to use a disposable light handle cover. This will eliminate the cleaning and re-sterilizing of the original OEM reusable light handle. The customer will need to replace the original OEM handle, with the light handle adapter that Litex Manufacturing, Inc. will provide the facility, through the light companies and other distributors.

7. **Discussion of Non-Clinical Tests Performed for the Determination of Substantial Equivalence are as follows:**

   No non-clinical tests were performed.

8. **Discussion of Clinical Tests Performed:**

   Clinical testing was not performed.

9. **Conclusions:**

   Based on the information provided in this submission we conclude that the Light Handle Adapters are substantially equivalent to the predicate and are safe and effective for its intended use.