K100234

January 5, 2010

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES
Center for Devices and Radiological Health
Document Control Center (HFZ-404)
9200 Corporate Boulevard
Rockville, MD 20850

FDA CDRH DMC
JAN 26 2010
Received

JUL - 8 2010

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.

The assigned 510(k) number is _____

1. Submitter Identification.

Maria T. Guma
Regulatory Affairs
HILLUSA CORPORATION
7215 N.W. 46th Street
Miami, Florida 33166

K24

2. Name of the Device:

Common Name:	HM-LAMP II Serie (Hill-Med)
Classification Name:	Lamp, Surgical
Class:	II
Classification number:	FTD, Regulation # 878.4580

3. Predicate Device Information:

ST. FRANCIS OPERATING THEATRE LAMPS, K003423. ST. FRANCIS MEDICAL EQUIPMENT CO., LTD. P.O. BOX 129, SHIEN CHUANG 24299. TAIPEI SHIEN, TAIWAN, R.O.C.

4. Device Description:
The HM-LAMP II Series are operating lamps with high performance. Flexible movement arm and mobile stand. Designed for minor surgical procedures as well as additional operating room needs.

5. Intended Use:
A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.

6. Comparison to Predicated Device:

The HM-LAMP II SERIES are used in exactly same manner as ST. FRANCIS OPERATING THEATRE LAMPS, both lamps series are intended for use as an excellent visible illumination of the surgical field or the patient.

The mainly differences between HM-LAMP II SERIES and ST. FRANCIS OPERATING THEATRE LAMPS are Weight and Dimension only.

7. Performance Standards

The device complies with:
The design, manufacturing and quality control of the device comply with:
ISO 9001-2000, CE and ISO 13485.
Attach all these certificated.

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

JUL - 8 2010

Hillusa Corporation
% Ms. Maria T. Guma
Regulatory Affairs
7215 N.W. 46th Street
Miami, Florida 33166

Re: K100234
Trade/Device Name: HM-LAMP II
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: Class II
Product Code: FTD
Dated: January 05, 2010
Received: April 14, 2010

Dear Ms. Guma:

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

Indications for Use

510(k) Number (if known) : K100234

Device Name: HM-LAMP II

Indications for Use:

HM-LAMP II is a device intended to be used to provide visible illumination of the surgical field or the patient. They are designed for minor surgical procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100234