K102149

AUG 13 2010

# 510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92

## 1.0 Submitter's Information

**Establishment Registration Name:**

Foshan Gaunying Electronics Co., Ltd.

4F, #4 Industry Country,
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Foshan, Guangdong, China 528000

**Contact Person of the Applicant:**

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## 2.0 Device Information

| | |
|---|---|
| Type of 510(k) submission: | Traditional |
| Device Common Name: | Infrared Lamp |
| Trade Name: | Infrared Lamp |
| Model: | FIR 51, SN-51 |
| Classification name: | lamp, infrared, therapeutic heating |
| Review Panel: | Physical Medicine |
| Product Code: | ILY |
| Regulation Class: | Class II |
| Regulation Number: | 21CFR 890.5500 |

## 3.0 Predicate Device Information

| | |
|---|---|
| Sponsor: | Chongqing Xinfeng Medical Instrument Co., Ltd. |
| Device: | Xinfeng Heating Lamp, including 3 different models CQ-27, CQ-36 and CQ-55A |
| 510(K) Number: | K043558 |

## 4.0 Device description

Gaunying Infrared Lamp (Model#: FIR 51, SN-51) has a high-quality glass ceramic plate (ceramic infrared). Glass ceramic plates are also used on hobs and when used in conjunction with illuminants guarantee intensive and safe infrared radiation.

## 5.0 Intended Use

The Infrared Lamp are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

## 6.0 Performance Summary

Testing of the Infrared Lamp (Model#: FIR 51, SN-51) includes functional performance testing and electrical safety testing. The device is manufactured to comply with the following international standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General)
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment

1:2004)). (General)

- UL 60601-1, first edition, 2003, deviations to IEC 60601-1

## 7.0 Non-clinical data

We conduct a performance testing with the subject device. For the subject device, let a person at the distance 30cm, 35cm and 40cm, set the treatment time at 15 minutes, and then we use an electronic thermometer to measure the temperature of skin temperature every minutes. The testing result shows that the skin temperature can rise to 40□ within 5 minutes which means that the subject device can maintain skin temperature at least 10 minutes in one treatment time (15 minutes).

## 8.0 Comparison to predicate device and conclusion

Compared with predicate device Xinfeng CQ-27, CQ-36 and CQ-55A Heating Lamps made by Chongqing Xinfeng Medical Instrument Co., Ltd. (K043558), the device Infrared Lamp (Model#: FIR 51 and SN-51) has same intended use with the predicate device. Although, there is a little different technological characteristics;

The infrared wavelength used in subject device and predicate device is deferent. The subject device uses 600 nm — 2000 nm infrared, which belongs to Near-infrared (0.75-1.4 μm) and Short-wavelength infrared (1.4-3 μm). The predicate device use 5 to 25 microns, which belongs to Long-wavelength infrared (8–15 μm) and far infrared (15-1,000 μm).

The human visible light is in wavelength 400–700 nm. So the subject device heating can be seen when it is working. The predicate device heating is not visible when it is working. That means the possibility of burns risk for subject device is less than the predicate device.

Whatever Near-infrared, Short-wavelength infrared, Long-wavelength infrared and Far infrared, they all can heat and therapy disease. The different wavelength will not affect the effectiveness of device.

We conduct a comparison testing with the subject device and predicate device. For the subject device, put an electronic temperature sensor at the distance 30cm, 35cm, 40cm and 45cm. Set the treatment time at 15 minutes, and then record the temperature at the end of setting time. The test ambient temperature condition: 25□. For the predicate device, put an electronic temperature sensor at the distance 8'', 10'' and 12''. Set the treatment time at 60 minutes, and then record the temperature at the end of setting time. The test ambient temperature condition: 25□. The result shows that both device can achive the temperature range 41-45□ which is an effective therapy temperature range.

The testing report shows that Infrared Lamp (Model#: FIR 51 and SN-51) is as

effective as predicate device.

The new device pass the safety testing, and the risk management report shows all the risk are under control.

So, the deference does not raise new questions of safety and effectiveness. The Infrared Lamp (Model#: FIR 51 and SN-51), is substantially equivalent to the predicate device.

**9.0 Submission date: Oct 21, 2009**

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

Foshan Gaunying Electronics Co., Ltd.
% Intertek Testing Services NA, Inc.
Mr. William J. Sammons
2307 E. Aurora Road Unit B7
Twinsburg, OH 44087

AUG 13 2010

Re: K102149
Trade/Device Name: Gaunying Infrared Lamp
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: July 29, 2010
Received: July 30, 2010

Dear Mr. Sammons:

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

**Statement of Indications for Use** K102149

510(k) Number (if known): AUG 13 2010

Device Name: Infrared Lamp
Model: FIR 51, SN-51

Indications For Use:

The Gaunying Infrared Lamp ( Model #: FIR 51, SN-51) are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K102149