K101988

FEB - 8 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: March 30, 2009

1. Company and Correspondent making the submission:

Name – Shanghai Lishen Scientific Equipment Co., Ltd.

Address – No.6788 SongZe Avenue, QingPu, Shanghai, China

Telephone – +86-21-649-53016

Fax – +86-21-64953025, 64953071

Contact – Mr. Ma Ying

Email – suhong@shanghai-lishen.com

2. Device :

Trade/proprietary name: Heal Force CO2 Incubator, Models HF90 and HF240

Common Name : CO2 Incubator

Classification Name : Accessory, Assisted Reproduction

Predicate Devices:

Predicate Model	Manufacturer	K Number	Submitted Device
Kendro Heracell CO2 Incubator-HERAcell	**FORMA SCIENTIFIC, INC**	**K002805**	**HF90**
Kendro Heracell CO2 Incubator-HERAcell	**FORMA SCIENTIFIC, INC**	**K023465**	**HF240**

3. Classifications Names & Citations :

21CFR 884.6120, MQG, CO2 Incubator, Class II

4. Description :

4.1 General

The HEAL FORCE CO2 Incubator is a piece of assisted reproductive laboratory equipment used for incubation of ova and embryos.

Structure

- The outer casing is made of electrolytically galvanized steel sheet and lacquered white （RAL 9002）.
- The control elements are made of plastic.
- The inner casing is made of stainless steel.

- **Internal Fittings:**
  - The pullout shelves are tilt-proof and adjustable over a height of 50 mm. Removal of shelves, carrier requires no tools, and they can be taken out together at a time.
- **Heating System:**
  - Large-surface heating cables are arranged on the outside of the inner casing, to heat the interior space. The heating cables are placed beneath the water reservoir, on the ceiling, on the upper part of the rear wall and in front of the outer door.
  - When the outer door is heated, condensation will not precipitate on the glass door. Therefore, the interior remains clearly visible in spite of the prevailing high humidity. Condensation may be formed if the outer door is left open for some time.

5. Indication for use : For Models HF90, HF240:

The intended use of these incubators is to provide an environment with controlled temperature, CO2 elevated humidity, and an automatic disinfection mode, for the development of ova or embryos at or near body temperature.

6. Comparison with predicate device :

Predicate Model	Manufacturer	K Number	Submitted Device
Kendro Heracell CO2 Incubator-HERAcell	**FORMA SCIENTIFIC, INC**	**K002805**	**HF90**
Kendro Heracell CO2 Incubator-HERAcell	**FORMA SCIENTIFIC, INC**	**K023465**	**HF240**

Comparison Table 01 for Model HF90, HF240

Element of comparison	Subject Device	Claimed SE Device
Company	Shanghai Lishen Scientific Equipment Co., Ltd	Kendro Laboratory Products, L.P.
FDA510(K) Number	N/A	K002805
Device Name	HEAL FORCE CO2 incubator	HERAcell CO2 Incubator
Model Number	HF90,HF240	HERAcell 150, HERAcell 240
Intended use(s)	For Models HF90 and HF 240, the intended use of these incubators is to provide an environment with controlled temperature, CO2, elevated humidity, and an automatic disinfection mode, for the development of ova or embryos at or near body temperature.	The intended use of this incubator is to provide an environment with controlled temperature; CO2 elevated humidity, and an automatic decontamination mode, for the development of ova or embryos at or near body temperature.

Labeling	The HEAL FORCE incubators are bench top or floor standing units. They control CO2 (T/C), temperature (by independent digital controller with a separate switching device), provide elevated humidity, and feature a decontamination mode (Same as HERAcell Contracon automatic disinfection routine) incorporating humid heat at 90°C. Consistent culture conditions throughout the interior are achieved by the air jacket temperature control and exact simulation of physiological conditions. Controlled parameters and alarm functions are microprocessor controlled.	The HERAcell CO2 incubators are bench top or floor standing units. They control CO2 (T/C), temperature (by independent digital controller with a separate switching device), provide elevated humidity, and feature a decontamination mode (Contracon automatic disinfection routine) incorporating humid heat at 90°C. Consistent culture conditions throughout the interior are achieved by the air jacket temperature control and exact simulation of physiological conditions. Controlled parameters and alarm functions are microprocessor controlled.
Power requirements	AC 230V 50/60Hz AC 120V 50/60Hz	AC 230V 50/60Hz AC 120V 50/60Hz
Ambient temperature	+18 °C to + 33 °C	+18 °C to + 33 °C
Specification:	Temperature: Range Ambient Temperature +3°C—+55°C Time deviation ±0.1 °C spatial deviation ±0.5 °C Recovery time(at 37°C) ≤10min （30 sec. door open, to 98% of initial value） CO2 control Set range 0—20% Control accuracy ±0.1% Recovery time(5%CO2) ≤5min (HF90)	Temperature: Range Ambient Temperature +3°C—+55°C Time deviation ±0.1 °C spatial deviation ±0.5 °C Recovery time(at 37°C) ≤10min （30 sec. door open, to 98% of initial value） CO2 control Set range 0—20% Control accuracy ±0.1% Recovery time(5%CO2) ≤5min (HERAcell 150)

	Recovery time(5%CO2) ≤10min (HF240)	Recovery time(5%CO2) ≤10min (HERAcell 240)
Relative Humidity	Constant humidity at 37℃ high-humidity mode: Approx. 95 % rH low-humidity mode: Approx. 90% rH	Constant humidity at 37℃ high-humidity mode: Approx. 95 % rH low-humidity mode: Approx. 90% rH
Energy used and / or delivered (110/120V 50/60Hz)	HF 90 650W HF 240 710W	HERAcell 150 640W HERAcell 240 640W

7. Safety and Performance Data :

Electrical, mechanical, environmental safety and performance testing have been accomplished according to standard EN/IEC 60601-1-2 for EMC considerations and EN/IEC 61010 for product safety.

8. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Shanghai Lishen Scientific Equipment Co., Ltd. concludes that HEAL FORCE CO2 Incubator, Models HF90 and HF240 is safe and effective and substantially equivalent to predicate devices as described herein.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Shanghai Lishen Scientific Equipment Co., Ltd.
c/o Mr. Charles Mack
Principal Engineer
International Regulatory Consultants, LLC
77325 Joyce Way
ECHO OR 97826

FEB - 8 2011

Re: K101988
Trade Name: Heal Force CO_2 Incubator (Models HF90 and HF240)
Regulation Number: 21 CFR §884.6120
Regulation Name: Assisted reproductive accessories
Regulatory Class: II
Product code: MQG
Dated: January 16, 2011
Received: January 31, 2011

Dear Mr. Mack:

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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101988

Device Name: HEAL FORCE CO2 Incubator

Indications For Use:

For Models HF90, HF240, the intended use of these incubators is to provide an environment with controlled temperature, CO2 elevated humidity, and an automatic disinfection mode, for the development of ova or embryos at or near body temperature.

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 Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K101988