MAR 2 2 2006

K053466

6. 510(k) Summary

In accordance with 21 CFR section 807.92 Hsiner is submitting the following 510(k) summary.

6.1. Submitter Information

Hsiner Company, LTD
No. 13, Tyan Shin St., Taya Hsiang
Taichung Hsien, Taiwan, ROC

Phone: +886-4-25664306

Registration No.: 3003862188
Owner/Operator No.: 9053474

6.2. Name of Device

Resuscitator:

Device Name Ventilator, Emergency, Manual (Resuscitator)

Product Code BTM

Regulation # 868.5915

Device Class 2

PEEP Valve:

Device Name Attachment, Breathing, Positive, Positive End Expiratory Pressure

Product Code BYE

Regulation # 868.5965

Device Class 2

6.3. Substantially equivalent to:

Resuscitator:

- Headstar Medical Products Manual Emergency Resuscitator (K002846).
- Ventlab Corporation V*Care Manual Resuscitator (K012842)
- Hudson RCI Lifesaver Single Patient Use Manual Resuscitator (K 944301)

PEEP Valve:

- Ambu Single Patient Use PEEP Valve (K923976).
- Hudson RCI Lifesaver Peep Valve (K902062)
- Engineered Medical Systems PEEP Valve (K983920)

6.4. Description of the device

Resuscitator:

The Hsiner Resuscitator is used to manually administer ventilation to patients requiring assisted ventilation in emergency and hospital settings.

The Resuscitator complies with ASTM 940-93 "Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans" and ISO 8382:1988 "Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans." The resuscitator is provided in three sizes, adult, child and infant, along with various attachments including face masks, reservoir valve sets, PEEP valves and oxygen tubing.

PEEP Valve:

The PEEP valve is an adjustable, spring actuated valve which when placed into a circuit provides positive end expiratory pressure for the patient. The PEEP vale is provided in two pressure ranges and several connector sizes complying wit ISO 5356-1 "Anesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets".

6.5. Intended Use of the Device

Resuscitator:

The Hsiner Resuscitator is used to manually administer ventilation to patients requiring assisted ventilation in emergency and hospital settings.

PEEP Valve:

The Hsiner PEEP Valve is used in conjunction with manual resuscitators and other ventilatory support equipment to provide positive end expiratory pressure.

6.6. Comparison to Predicate Devices

The Hsiner Resuscitators and PEEP Valves are equivalent in design, materials and performance to the Predicate devices listed in Section 8.4. All the predicate devices listed in Section 8.4 utilize the same principles of operation and have the same intended use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2006

Hsinder Company, Limited
C/O Mr. Tom Shanks
Regulatory Specialist
MDVentures
29201 Via Norte
Temecula, California 92591

Re: K053466
Trade/Device Name: Hsiner PEEP Valve
Regulation Number: 868.5915, 868.5965
Regulation Name: Manual emergency ventilator
Regulatory Class: II
Product Code: BTM, BYE
Dated: March 13, 2006
Received: March 16, 2006

Dear Mr. Shanks:

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 (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 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.

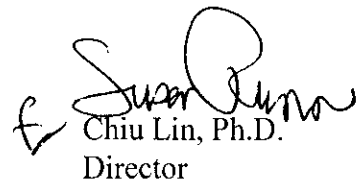
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 continue 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K053466

Device Name: Hsiner PEEP Valve

Indications for Use:

The Hsiner PEEP Valve is used in conjunction with manual resuscitators and other ventilatory support equipment to provide positive end expiratory pressure.

Prescription Use ___X___ 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)

[illegible] General Hospital
[illegible] Dental Devices
K053466