JUL 14 1998

CHEEN HOUNG ENTERPRISE CO. LTD.

23, ALLEY 11, LANE 65, SAN DREEN ST., SHULIN (238) TAIPEI SHENG, TAIWAN, R.O.C.
FAX: 886-2-2689-2468 TEL: 886-2-2689-2001

K981415

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

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 Cheen Houng Enterprise Co., Ltd. 0-20 Cm H2O PEEP Valves are similar in intended use, design, material selection, performance and function to Life Design PEEP FLO PEEP Valves which are currently legally and safely marketed in the United States. No new technological characteristics that could affect safety or effectiveness have been introduced.

Therefore, it is our conclusion that the Cheen Houng Enterprise Co., Ltd. 0-20 Cm H2O PEEP Valves are safe and effective for their intended function.

Signature _____ Date 4/13/99
Jay Wang
President of Cheen Houng Enterprise Co., Ltd.

MALAYSIA PLANT: PLAXTRON INDUSTRIAL (M) SDN, BHD
Plot 28, Free trade Zone, Jelapang II, 30020 Ipoh, Perak, Malaysia
Tel: 60-5-264-608 Fax: 60-5-264-582

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1998

Mr. Jay Wang
Cheen Houng Enterprise Co., LTD
23 Alley 11 Lane 65 San Dreen Street
Shulin (23805) Taipei Sheng Taiwan R.O.C.

Re: K981415
"0-20 Cm H20 PEEP Valve"
Regulatory Class: II (two)
Product Code: 73 BYE
Dated: April 10, 1998
Received: April 20, 1998

Dear Mr. Wang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

The Cheen Houng 0-20 Cm H2O PEEP Valve is indicated as an accessory to add positive end expiratory pressure breathing capability to a Manual Resuscitator. Fits 19 mm Male Conical exhalation ports.

Caution: Federal Law restricts this device to use by or on the order of a physician.

Paul L. Modes 7-14-98

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981415

Prescription Device