ENTER MEDICAL COPORATION
No. 16-1, Lane 564, Wen Hua San Road, Gui Shan Xiang,
Tao Yuan Hsien, Taiwan, ROC, 333
Tel: 886-3-3283653 Fax: 886-3-3285723

MAR 1 1 200

K042556

ShineBall®

" 510(k) SUMMARY "

Submitter's Name: ***ENTER Medical Corporation***
No. 16-1, Lane 564, Wen Hua San Road, Gui Shan Xiang,
Tao Yuan Hsien, 333,Taiwan

Date summary prepared: September 15, 2004

Device Name:

Proprietary Name: *ShineBall PVC Manual Resusciator, ENT-1001, ENT-1003, ENT-1005*
ShineBall Silicone Manual Resusciator, ENT-1022, ENT-1024, ENT-1014

Common or Usual Name: Manual Resusciators

Classification Name: Ventilator, Emergency, Manual (Resusciator)
21 CFR 868.5915

Indications for Use:

To be used in emergency situations to provide lung ventilation to individuals whose breathing is inadequate..

Description of the device:

ShineBall manual emergency resuscitator is a portable device used in life emergency situations to provide lung ventilation to individual whose breathing is inadequate. An optional ShineBall mask is recommended for use with a resuscitator to cover the patient's nose and mouth as a port to receive the patient connector of the resuscitator. A standard reservoir bag is to be used with the ventilation bag when the oxygen gas is supplied to the patient.

The performances of the manual resuscitators are intended for operator-powered types. Operator-powered resuscitator device is a device by which the ventilation of the lung is produced by operator's compressing the air out of the compressible part of the device. To reach the best effect of the clinical situations, *adult, child* and *infant* sizes of the resuscitators are designed according to body mass ranges. For safety consideration the *pressure limiting valve* is designed optionally for those who are not so skillful to operate the device. By adding the pressure limiting valve into the setting of the device, the pressure of the lung ventilation can be controlled easily according to patient's individual requirement.

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To lighten the financial burden of the patient or medical facilities, the material of *Silicone, which can be autoclaved,* is provided for reuse. To lower the cross-infection hazard the material *PVC* are used for single use and disposable ones.

Performance Testing:

Performance and Specifications of the SnineBall manual emergency resuscitator are consistent with all requirements for this device type specified by:

ASTM 920: Standard Specification for Minimum Performance and Safety Requirements for Resusciators Intended for Use with Humans;

ISO 8382: 1988 (E) : Resusciators Intended for Use with Humans;

ISO 5356-1: 1987: Anesthetic and Respiratory Equipment, Conical Connectors – Part 1: Cones and Sockets.

Biocompatibility Testing:

All of the SnineBall manual emergency resuscitators passes:

- Cytotoxicity study – ISO 10993-5
- Skin irritation study – ISO 10993-10
- Skin sensitization study – ISO 10993-10

Legally marketed device for substantial equivalence comparison:

HEADSTAR Manual Resuscitator (**K002846**)

Conclusion:

The predicate device and the new device are the same technical characteristics. There are including adult, child, and infant sizes. Besides, the material of *Silicone, which can be autoclaved,* is provided for reuse, the material *Rubber* for the predicate device and *PVC* for the new device is used for single use and disposable ones.

The comparison to the predicate device demonstrates that the new device is safe, effective, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2005

Mr. Tzong-Fuh Kuo
Enter Medical Corporation
No. 16-1, Lane 564, Wen Hua San Road
Gui Shan Xiang,
Tao Yuan Hsien, 333
TAIWAN

Re: K042556
Trade/Device Name: ShineBall PVC Manual Resuscitator, ENT-1001, ENT-1003, ENT-1005 ShineBall Silicone Manual Resusciator, ENT-1022, ENT-1024, ENT-1014
Regulation Number: 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: January 5, 2005
Received: January 22, 2005

Dear Mr. Fuh Kuo:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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 begin 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) 276-0120. 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/industry/support/index.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

Enclosure

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Indications for Use

510 (K) NUMBER (IF KNOW): **K042556**

DEVICE NAME: ShineBall PVC Manual Resusciator, ENT-1001, ENT-1003, ENT-1005;
ShineBall Silicone Manual Resusciator, ENT-1022, ENT-1024, ENT-1014

INDICATIONS FOR USE:

To be used in emergency situations to provide lung ventilation to individuals whose breathing is inadequate.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off
of Anesthesiology, General Hospital,
ion Control, Dental Devices
Number K042556