DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Dr. Tien-Hsing Yang
Headstar Medical Products Co., Ltd.
No. 23, Lane 431, HWA Chen Road
Hsin-Chuang City, Taipei Hsien
TAIWAN, ROC 242

Re: K002846
Headstar's Manual Emergency Resuscitator
Regulation Number: 868.5915
Regulatory Class: II (two)
Product Code: 73 BTM
Dated: April 14, 2001
Received: April 18, 2001

Dear Dr. Yang:

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,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

HEADSTAR MEDICAL PRODUCTS CO., LTD.
NO 23, LANE 431, HWA CHEN ROAD, HSIN-CHUANG CITY, TAIPEI HSIEN, TAIWAN, ROC 242
TELEPHONE: 886-2-89917623 TELEFAX: 886-2-89917703

K002846

510 (K) NUMBER (IF KNOW): _____

DEVICE NAME: HEADSTAR MANUAL RESUSCITATOR

INDICATIONS FOR USE:

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

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

Concurrence of CDRH, office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002846

Prescription Use ✓ OR Over – The – Counter – Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)