



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

Ms. Ana Maria Romero
Quality Assurance
Hersill, S. L.
Puerto De Navacerrada, 3
Mostoles (Madrid)
Spain 28935

SEP 17 2010

Re: K094003

Trade/Device Name: Revivator
Regulation Number: 21 CFR 868.5915
Regulation Name: Manual Emergency Ventilator
Regulatory Class: II
Product Code: BTM
Dated: September 10, 2010
Received: September 10, 2010

Dear Ms. Romero:

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.

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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 CDRII'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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



HERSILL, S.L.

Equipos Médicos - Medical Devices
C/ Puerto de Navacerrada, 3
28935 MOSTOLES - (Madrid) - Spain
Tel.: +34 91 616 41 11 - Fax +34 91 616 46 92
www.hersill.com



4. INDICATIONS FOR USE STATEMENT

K094003

Indications for Use

SEP 17 2010

510(k) Number (if known): _____

Device Name: REVIVATOR

Indications for Use:

The Revivator resuscitator is intended for pulmonary resuscitation.

The adult resuscitator is for people with a body weight of more than 30 kg (66 lbs)

The child resuscitator is for children with a body weight between 7 and 30 kg (15-66 lbs)

The infant resuscitator is for infants with a body weight up to 7 kg (15 lbs)


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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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