AUG 1 5 2002

Special 510(k): Device Modification

K022345

510(k) Summary

General Information

Classification	Class III
Trade Name	AutoPulse™ Resuscitation System Model 100
Submitter	Revivant Corporation 775 Palomar Avenue Sunnyvale, CA 94085 408-524-3500
Contact	Susanne T. Smith, M.S. Vice President, Clinical & Regulatory Affairs

Intended Use

The AutoPulse Resuscitation System Model 100 is intended to be used as an adjunct to manual CPR, on adult patients only, in cases of clinical death as defined by lack of spontaneous breathing and pulse.

Predicate Devices

K011046	AutoPulse Model 100
K851139	Thumper Model 1005

Device Description

AutoPulse Resuscitation System Model 100 ("Device") is an automated, portable, battery powered device that compresses the chest of an adult human as an adjunct to manual CPR. The Device consists of a single use chest compression assembly (CCA) that includes a patient liner, and a reusable platform that contains a user control panel, a drive mechanism, a control system, and a power system (rechargeable battery).

Materials

All materials used in the manufacture of the AutoPulse Resuscitation System Model 100 are suitable for this use and have been used in numerous previously cleared products.

Special 510(k): Device Modification

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices.

Summary of Substantial Equivalence

The AutoPulse Resuscitation System Model 100 is equivalent to the predicate products. The indications for use, basic overall function, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2002

Ms. Susanne T. Smith
VP Clinical and Regulatory Affairs
Revivant Corporation
775 Palomar Avenue
Sunnyvale, CA 94085

Re: K022345
Trade/Device Name: AutoPulse Resuscitation System, Model 100
Regulation Number: 21 CFR 870.5200
Regulation Name: External cardiac compressor
Regulatory Class: III
Product Code: DRM
Dated: July 18, 2002
Received: July 19, 2002

Dear Ms. Smith:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k): Device Modification

Indications for Use

510(k) Number (if known):	This application K022345
Device Name:	AutoPulse™ Resuscitation System Model 100
Indications for Use:	The AutoPulse Resuscitation System Model 100 is intended to be used as an adjunct to manual CPR, on adult patients only, in cases of clinical death as defined by lack of spontaneous breathing and pulse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K022345