DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2004

Ambu, Inc.
c/o Mr. Sanjay Parikh
Technical and Regulatory Affairs Manager
611 North Hammonds Ferry Road
Linthicum, MD 21090-1356

Re: K032421
Trade Name: Ambu Pediatric Multi-Function Defibrillation Electrodes
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: 74 MKJ, MLN
Dated: December 01, 2003
Received: December 02, 2003

Dear Mr. Parikh:

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 (301) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 032421

Device Name: Ambu Paediatric Multi-function Defibrillation Electrode

Indications For Use:

Ambu Paediatric Multi-Function Defibrillation Electrodes are used for defibrillation, pacing, monitoring ECG applications and synchronized cardioversion.
The Paediatric Multi-Function Defibrillation Electrodes may be used with Class III type of external defibrillators (automated external defibrillators) or class II type of transcutaneous external pacemakers (pulse amplitude not to exceed 200mA in pulse duration not to exceed 200 m sec.
The electrode can be used with mono- and biphasic defibrillators.
The electrode is intended for use on pediatric patients whose weight is less than 10kg (22lbs).
Disposable electrode, for single use, only.
The electrode is intended for use on defibrillators who's output is maximum 100 Joule.
Individual catalogue numbers are labeled for specific use primarily based on the interface connector and cable system which defines the host external device.

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

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032421