K100129

510(k) Summary

1. 510(k) owner:
   Ambu A/S
   Baltorpbakken 13
   2750 Ballerup
   Denmark
   Tel.: +45 72252000
   Fax.: +45 72252050

   JUN 11 2010

   Contact person:
   Anne Bielefeldt
   Regulatory Affairs Specialist

2. Preparation date of the 510(k) summary: April 2010

3. Name of device:

Device Common name:	Disposable ECG electrode
Device Trade name:	Ambu® Blue Sensor NEO Ambu® Blue Sensor NEO X
Classification Name:	Electrode, Electrocardiograph. 21 CFR 870.2360
Product Code:	DRX

4. Identifies the legally marketed device to which equivalence is claimed

Manufacturer	Trade Name	510k number	Product code
Ambu A/S	Ambu® Blue Sensor NF	K902407	DRX
Ambu A/S	Ambu® Blue Sensor BRS	K921579	DRX
Neotech Products, Inc.	Micro NeoLead	K011564	DRX
Ambu A/S	Ambu® Blue Sensor NEO/NEO X	K053550	DRX

5. Description of device
   Ambu® Blue Sensor NEO/NEO X is non-sterile, self-adhesive ECG electrodes. Ambu® Blue Sensor NEO/NEO X should only be used by or on the order of a physician.
   Ambu® Blue Sensor NEO/NEO X is single patient use disposable devices.

   Ambu® Blue Sensor NEO/NEO X is a multi-layer construction containing a pre-attached lead wire with an attached connector, a top disc, a top film, a sensor, a hydrogel, and a medical adhesive.

   The NEO/NEO X electrodes can be used for all pediatric populations (including neonates)
   The adhesive on the NEO/NEO X electrodes is suitable in the high humidity environment in the incubators and still gentle to the fragile neonatal skin.

6. The intended use
   The Ambu® Blue Sensor NEO and Ambu® Blue Sensor NEO X electrodes are made for ECG monitoring of neonatal and paediatric patients. The ECG electrodes are applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram. The electrodes are for single patient use only.

7. Summary of the technological characteristics in comparison to the predicate devices
   Ambu® Blue Sensor NEO/NEO X is a multi-layer construction containing a pre-attached lead wire with an attached connector, a top disc, a top film, a sensor, a hydrogel and a medical adhesive.
   The technological characteristics of Ambu® Blue Sensor NEO/NEO X are identical to the predicate devices: (See section 4 of this summary).

8. Brief discussion of the nonclinical tests submitted
   The non-clinical tests performed are laboratory tests to ensure the electrical and mechanical functionality of the electrode meets the standard ANSI/AAMI EC12:2000 – Disposable ECG Electrodes. All test are passed

   The biological safety of the Ambu® Blue Sensor NEO/NEO X has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. Tests were selected on the basis of ISO 10993-1 – Biological evaluation of Medical Devices:
   - Cytotoxicity (ISO 10993-5)
   - Sensitization (ISO 10993-10)
   - Intracutaneous reactivity test (ISO 10993-10)

   Result: All tests were passed.

9. Clinical test
   Not Applicable

10. Conclusions drawn from the nonclinical, clinical and biocompatibility tests
    The Ambu® Blue Sensor NEO/NEO X meet the mandatory performance standard requirements under ANSI/AAMI EC12:2000 – Disposable ECG electrodes.
    The biocompatibility of the Ambu® Blue Sensor NEO/NEO X has been established.
    It is concluded that Ambu® Blue Sensor NEO/NEO X is as safe, as effective and performs as well as or better than the legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUN 11 2010

Ambu Inc.
c/o Mr. Sanjay Parikh
Vice President Operations
6740 Baymeadow Dr.
Glen Burnie, MD 21060

Re: K100129
Trade/Device Name: Ambu® Blue Sensor NEO and Ambu® Blue Sensor NEO X
Regulatory Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrodes
Regulatory Class: Class II (Two)
Product Code: DRX
Dated: June 7, 2010
Received: June 8, 2010

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 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); 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 CDRH'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,

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): K100129

Device Name: Ambu® Blue Sensor NEO and Ambu® Blue Sensor NEO X

Indications For Use:

The Ambu® Blue Sensor NEO and Ambu® Blue Sensor NEO X electrodes are made for ECG monitoring of neonatal and paediatric patients. The ECG electrodes are applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram. The electrodes are for single patient use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 K100129