K051529

AUG 4 – 2005

510(k) Summary

1. 510(k) owner:
   Ambu A/S
   Baltorpbakken 13
   2750 Ballerup
   Denmark
   Tel.: +45 72252000
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   Contact person:
   Poul Ottosen
   Corporate Quality Manager

   Preparation date of the 510(k) summary: 1. June 2005

2. Name of device:

Device Common name:	Ground Electrode Disposable Ground Plate Electrode Disposable Ground Electrode
Device Trade name:	Ambu Neuroline Ground
Classification Name:	Electrode, Cutaneous. 21 CFR 882.1320
Product Code:	GXY

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

Manufacturer	Trade Name	Product code
Viasys Healthcare Nicolet Biomedical Instruments	Disposable Ground Plate Electrode	GXY
Oxford Instruments Medical Medelec Instruments	TECA NCS 2000 Disposable Ground Electrode	GXY

4. Description of device
   Ambu Neuroline Ground electrode should only be used by or on the order of a physician.
   Ambu Neuroline Ground electrode is used to ensure the presence of the same electrical potential at the amplifier and the measuring point during a neurophysiological examination.
   Ambu Neuroline Ground electrode is provided non-sterile. Ambu Neuroline Ground electrode is a single patient use disposable device.
   Ambu Neuroline Ground electrode is a multi-layer construction containing a hydrogel, a conductive film and a lead wire.

5. The intended use
   Ground electrode for standard neurophysiological examinations.

6. Summary of the technological Characteristics
   The technological characteristics of the Ambu Neuroline Ground electrode are identical to the predicate devices.
   The electrode is a multi-layer construction consisting of Hydrogel, conducting film, non-wowen backing material and lead wire with 1,5 mm touch proof connector.

7. 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

8. Brief discussion of the clinical tests submitted
   No clinical tests are performed

9. Conclusions drawn from the nonclinical and clinical tests
   Aging test of Ambu Neuroline Ground electrode and comparison test to predicate devices have been performed. From the results it has been concluded that Ambu Neuroline Ground electrode has equivalent electrical and mechanical functionality as the predicate device.
   The device meets mandatory performance standards.
   The biocompatibility of the electrode has been established.
   It is concluded that Ambu Neuroline Ground electrode is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 - 2005

Mr. Sanjay Parikh
Technical and Regulatory Affairs
Ambu Inc.
6740 Baymeadow Drive
Glen Burnie, Maryland 21060

Re: K051529
Trade/Device Name: Ambu Neuroline Ground
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: July 13, 2005
Received: July 18, 2005

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 (240) 276-0115. 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,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051529

Device Name: Ambu Neuroline Ground

Indications For Use:

The intended use of Ambu Neuroline Ground electrode is to ensure the presence of the same electrical potential at the amplifier and the measuring point during a neurophysiological examination of muscles and/or nerves. The electrode is for single patient use only.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051529