

AUG 4 – 2005

**510(k) Summary**1. 510(k) owner:

Ambu A/S  
 Baltorpbakken 13  
 2750 Ballerup  
 Denmark  
 Tel.: +45 72252000  
 Fax.: +45 72252050

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

<u>Manufacturer</u>	<u>Trade Name</u>	<u>Product code</u>
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-woven 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.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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.

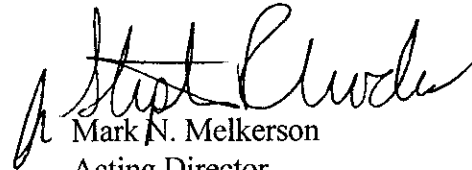
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2- Mr. Sanjay Parikh

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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

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   
(Part 21 CFR 801 Subpart D)

AND/OR

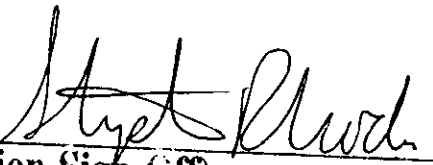
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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