Revised Summary

K071185

510(k) Summary

MAY 30 2007

1. 510(k) owner:
   Ambu A/S
   Baltorpbakken 13
   DK-2750 Ballerup
   Denmark
   Tel.: +45 72252000
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   Contact person:
   Anne Bielefeldt
   Regulatory Affairs Specialist

2. Preparation date of the 510(k) summary: April 2007

3. Name of device:
   Device Common name: Disposable Monopolar needle electrode

4. Device Trade name: Neuroline, Disposable Monopolar needle electrode

5. Classification Name: Electrode, needle.
   21 CFR 882.1350

6. Product Code: GXZ

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

Manufacturer	Trade Name	Product code
Ambu A/S	Neuroline, Disposable Monopolar needle electrode	GXZ
Viasys Healthcare Inc.	Medelec Elite Disposable Concentric Needle Electrode	IKT

8. Description of device

The Ambu Neuroline Disposable Monopolar needle electrode is a Single Patient EMG needle electrode and is used to measure an EMG signal when connected to the EMG equipment. The Ambu Neuroline Disposable Monopolar needle is manufactured in different lengths and diameters.

The Ambu Neuroline Disposable Monopolar needle is connected to the EMG equipment through a 1.5 mm touch proof connector according to DIN 42 802 either with a pre-attached cable or as a non-cable version to be used with Ambu's reusable cable for the Ambu Neuroline Monopolar. The Ambu Neuroline Disposable Monopolar needle electrode is a sterile product.

9. The intended use

Ambu Neuroline Disposable Monopolar needle electrodes is used for electromyography (EMG) recording for examination of the peripheral neuromuscular system, by registration of the electrical activity from the muscles. This is used to assess whether muscle impairment is due to disturbances in the motor neurones, the motor nerve fibres or in the muscle itself. It is used mainly to tell the difference between muscle diseases and nerve diseases.

10. Indication for Use

The Neuroline, Disposable Monopolar needle electrodes are made for muscle activity recording for Electromyography (EMG) applications. The electrodes are for single patient use only.

11. Summary of the technological Characteristics

Ambu Neuroline Disposable Monopolar needle electrodes consist of a solid needle made from stainless steel coated with a low friction polymer. The Ambu Neuroline Disposable Monopolar needle electrode is used with a reference electrode and a ground electrode.

12. Brief discussion of the nonclinical tests submitted

The non-clinical tests performed are laboratory tests to verify the functionality of the Ambu Neuroline Disposable Monopolar needle electrode. The Ambu Neuroline Disposable Monopolar needle electrode is tested for penetration force, friction force and electrical properties. The verification of the sharpness and the friction of the needle was performed according to DIN 13097.
Ageing tests are performed to verify and ensure the functionality during the shelf life of the product.

13. Brief discussion of the clinical tests submitted

No clinical tests were performed for the updated version of the Ambu Neuroline Disposable Monopolar needle because it has the same intended use and similar characteristics as the currently commercially available Ambu Neuroline Disposable Monopolar needle electrode.

14. Biocompatibility testing

The biological safety of the Ambu Neuroline Disposable Monopolar needle electrode 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 Device.

The following tests were performed and passed:

- Cytotoxicity assay in vitro
- Contact hypersensitivity in the guinea pig - Maximization study
- Intracutaneous test in the rabbit
- Systemic Injection test in the mice

15. Conclusions drawn from the nonclinical, clinical and biocompatibility tests

From the results of the non clinical verification test and biocompatibility test, it has been concluded that Ambu Neuroline Disposable Monopolar Needle electrode fulfils the product specifications set for the design.
It is concluded that Ambu Neuroline Disposable Monopolar Needle electrode is a safe and effective Monopolar needle electrode and comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ambu Inc.
c/o Mr. Sanjay Parikh
Technical and Regulatory Affairs
6470 Baymeadow Drive
Glen Burnie, Maryland 21060

MAY 30 2007

Re: K071185
Trade/Device Name: Neuroline, Disposable Monopolar needle electrode
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: April 26, 2007
Received: April 30, 2007

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) 276-0120. 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 (240) 276-3150 or at Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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: K071185

Device Name: **Ambu Neuroline, Disposable Monopolar needle electrode**

Indications For Use:

The **Neuroline, Disposable Monopolar needle electrodes** are made for muscle activity recording for Electromyography (EMG) applications. The electrodes are 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 K071185