K071186

510(k) Summary

1. 510(k) owner:
   Ambu A/S
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   DK-2750 Ballerup
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   Tel.: +45 72252000
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   JUL 30 2007

   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 Concentric needle electrode

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

5. Classification Name: Electrode, needle, diagnostic electromyography 21 CFR 890.1385

6. Product Code: IKT

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

Manufacturer	Trade Name	510k number	Product code
Ambu A/S	Neuroline, Disposable Concentric needle electrode	K973529	IKT
Viasys Healthcare Inc.	Medelec Elite Dispos-able Concentric Needle Electrode	K961013	IKT
Medtronic Inc.	DCNtm Disposable Concentric Needle Electrode	K931966	IKT

8. Description of device

The Ambu Neuroline Concentric Needle is a Single Patient EMG Needle Electrode and is used to measure an EMG signal when connected to the EMG equipment through a 5 pins reusable cable. The Electromyogram (EMG) records electrical activity within the muscle. It is used mainly to tell the difference between muscle diseases and nerve diseases. The Ambu Neuroline Concentric Needle is a sterile product.

9. The intended use

Ambu Neuroline Disposable Concentric 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. Indications for Use

The Neuroline, Disposable Concentric 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 Concentric Needle consists of a cannula made of stainless steel and an inner conductor. In between these two conductors there is an insulation layer. The inner conductor is the active measure point and the outer conductor of stainless steel is the reference point. The Stainless steel cannula is coated with a low friction polymer.

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 Concentric needle electrode. The Ambu Neuroline Disposable Concentric needle electrode is tested for penetration and friction force and electrical properties. The verification of the penetration and the friction force of the needle were 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 Concetric needle because it has the same intended use and similar characteristics as the currently commercially available Ambu Neuroline Disposable Concentric needle.

14. Biocompatibility testing - Summary

The biological safety of the Ambu Neuroline Concentric Needle 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:

- 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 non clinical, clinical and biocompatibility tests

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

JUL 30 2007

Ambu A/S
% Ambu Inc.
Mr. Sanjay Parikh
Technical & Regulatory Affairs Specialists
US Agent and FDA Contact
6740 Baymeadow Drive
Glen Burnie, MD 21060

Re: K071186
Trade/Device Name: Ambu Neuroline, Disposable Concentric Needle Electrode
Regulation Number: 21 CFR 890.1385
Regulation Name: Diagnostic electromyograph needle electrode
Regulatory Class: II
Product Code: IKT
Dated: July 23, 2007
Received: July 24, 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) 276-0115. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

7/30/07

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: K071186

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

Indications For Use:

The **Neuroline, Disposable Concentric 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 K071186