510(k) Summary

K093825

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

JAN 13 2010

Contact person:
Anne Bielefeldt
Regulatory Affairs Specialist

2. Preparation date of the 510(k) summary: November 2009

3. Device Common name: Neuroline Single Patient, Hypodermic Needle Electrode

4. Device Trade name: Ambu® Neuroline Disposable Inoject needle electrode

5. Classification Name: Electrode, Needle, Diagnostic Electromyograph
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	Ambu Neuroline Monopolar needle electrode	K071185	GXZ
Ambu A/S	Ambu Neuroline Inoject needle electrode	K001869	IKT
Viasys Healthcare Inc.	TECA Disposable MyoJect Needle Electrodes	K973444	IKT
Alpine Biomed	*Bo-Ject Needles*	K002992	IKT

8. Description of device

The Ambu Neuroline Disposable Inoject needle electrode is a Single Patient needle electrode for Electromyography (EMG) guided injections. The needle electrode is designed for Botulinum Toxin therapy and nerve block procedures.

The Ambu Neuroline Disposable Inoject needle is manufactured in different lengths and diameters.

The Ambu Neuroline Disposable Inoject needle is connected to the EMG equipment through a touch proof connector with a pre-attached cable.

The Ambu Neuroline Disposable Inoject needle electrode is a sterile product.

9. The intended use

Electromyography (EMG) guided injections

10. Indication for use

Electromyography (EMG) Needle Electrode designed for Botulinum Toxin therapy and nerve block procedures.
For single patient use only.

11. Summary of the technological Characteristics

Ambu Neuroline Disposable Inoject needle electrodes consist of a coated needle made from stainless steel. The Ambu Neuroline Disposable Inoject 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 Inoject needle electrode. The Ambu Neuroline Disposable Inoject needle electrode is tested for penetration force and friction force, electrical properties and mechanical properties.

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 Inoject needle because it has the same intended use and similar characteristics as the currently commercially available Ambu Neuroline Disposable Inoject needle electrode.

14. Biocompatibility testing

The biological safety of the Ambu Neuroline Disposable Inoject 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 Inoject Needle electrode fulfils the product specifications set for the design.
It is concluded that Ambu Neuroline Disposable Inoject Needle electrode is a safe and effective Inoject needle electrode and comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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

JAN 18 2010

Re: K093825
Trade/Device Name: Ambu® Neuroline Disposable Inoject Needle Electrode
Regulation Number: 21 CFR 890.1385
Regulation Name: Diagnostic Electromyograph Needle Electrode
Regulatory Class: II
Product Code: IKT
Dated: December 11, 2009
Received: December 14, 2009

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

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K093825

Device Name: Ambu® Neuroline Disposable Inoject Needle Electrode

Indications For Use: Electromyography (EMG) Needle Electrode designed for Botulinum Toxin therapy and nerve block procedures. 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)

CG

Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K093825