K112034

Special 510(k) Premarket Notification
CareFusion 209, Inc.
TECA™ ELITE Disposable Concentric Needles
510(k) Summary

AUG 12 2011

Submission Date: 10 July 2011

Submitter:
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Manufacturing Site:
CareFusion Manufacturing Ireland 241, Ltd.
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Trade Name: TECA™ ELITE Disposable Concentric Needles

Classification Name: Diagnostic electromyograph needle electrode

Classification Regulation: 21 CFR §890.1385

Product Code: IKT

Substantially Equivalent Devices:

New CareFusion Model	*510(k) Number*	*Predicate Manufacturer / Model*
TECA™ ELITE Disposable Concentric Needles	K961013	Medelec, Limited (now owned by CareFusion) / Disposable Needle Electrode

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Device Description:

CareFusion 209, Inc. TECA™ ELITE Disposable Concentric Needles (TECA™ ELITE Needles) are disposable, single use, sterile products intended to sense subcutaneous bioelectrical activity, or to stimulate nerve or muscular response by insertion into the patients muscle(s) through the skin where the recording area can differentiate between individual motor units. TECA™ ELITE Needles are connected to an electromyographic (EMG) device through a cable. The EMG device detects and displays the biopotential information to the user.

TECA™ ELITE Needles consist of a stainless steel tube with a conductive core. A polyesterimide isolative coating resides between the core and the stainless steel tube. The exterior surface of the needle is dipped in a low-friction lubricant. TECA™ ELITE Needles are passive devices, and do not contain electrical hardware components or software.

The following device modifications were made to the TECA™ ELITE Needles:

- Modification of the core material;
- Addition of a low friction lubricant to the exterior surface of the needle; and
- Modification of the packaging materials.

Intended Use:

TECA™ ELITE Disposable Concentric Needles are intended for use with recording, monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals including electromyograph (EMG) and nerve potential signals.

Technology Comparison:

TECA™ ELITE Needles employ the same technological characteristics as the predicate device.

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Summary of Performance Testing:

Biocompatibility

A comparison of the TECA™ ELITE Needles core material was made with the core material from the following devices:

- *K991522, FHC Micro Targeting Electrode; and*
- *K033173, FHC Micro Targeting Electrode.*

Biocompatibility verification was performed on direct patient contact materials comprising the TECA™ ELITE Needles that were affected by the device modifications in accordance with and the applicable portions of the following Standards:

- *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Additionally, a comparison of the low friction lubricant characteristics used on the exterior surface of the TECA™ ELITE Needles was made to the low friction lubricant characteristics used on the following device:

- *K111131, TECA™ elite Disposable Monopolar Needles.*

Verification results and device material comparisons indicated that the TECA™ ELITE Needles comply with their predetermined specifications, and with the applicable portions of the Standard.

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Performance Testing – Bench

Performance testing was performed on device characteristics of the TECA™ ELITE Needles that were affected by the device modifications in accordance with internal requirements and the applicable portions of the following Standards:

- *ASTM F88 – 07, Standard Test Method for Seal Strength of Flexible Barrier Materials*
- *ASTM F1929 – 04, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*
- *ISO 7864: 1993, Sterile hypodermic needles for single use*

Performance testing related to internal requirements consisted of:

- *Verification of lubricant performance;*
- *Validation of insertion force; and*
- *Validation of recording characteristics including noise and impedance testing.*

Verification and validation results indicated that the TECA™ ELITE Needles comply with their predetermined specification and with the applicable Standard.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to the TECA™ ELITE Needles. The results of these activities demonstrate that the TECA™ ELITE Needles are safe and effective when used in accordance with the intended use and labeling.

Therefore, the TECA™ ELITE Needles are considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CareFusion 209 Inc.
% Mr. Glen Hermanson
Regulatory Affairs Manager - Manufacturing
1850 Deming Way
Middleton, WI 53562

AUG 12 2011

Re: K112034
Trade/Device Name: TECA™ ELITE Disposable Concentric Needles
Regulation Number: 21 CFR 890.1385
Regulation Name: Diagnostic Electromyograph Needle Electrode
Regulatory Class: Class II
Product Code: IKT
Dated: 10 July 2011
Received: 15 July 2011

Dear Mr. Hermanson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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 (if known): K112034

Device Name: TECA™ ELITE Disposable Concentric Needles

Indications for Use: TECA™ ELITE Disposable Concentric Needles are intended for use with recording, monitoring and stimulation/recording equipment for the stimulation/recording of biopotential signals including electromyograph (EMG) and nerve potential signals.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

John Grimes

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

510(k) Number K112034