

SEP 17 2003

Section 6.0 510(k) Summary

Submitter: Clinical Innovations, Inc.
 Name: Wm. Dean Wallace
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Proprietary Names: Fetal Spiral Electrode
 Common/Usual Name: Fetal Scalp Electrode
 Classification Name: Fetal Scalp Circular Electrode and applicator

The legally marketed devices to which equivalence is claimed are: Life Trace Fetal Spiral Electrode (K943732), Corometrics Spiral Electrode (K792669), HP Spiral Scalp Electrode (K771553), Medi-Trace Fetal Monitoring Spiral Electrode (K904745), MAI Fetal Scalp Electrode (K872057), Surgicraft Copeland Disposable (K844608).


Description of the device: The device consists of a stainless steel spiral needle electrode. It is fixed to the fetal scalp by penetration of the skin by the spiral needle and thereby obtains the fetal ECG signal. A guide tube and a drive tube are required to place the electrode and are then removed before monitoring is begun. A stainless steel reference electrode is included close to the body housing the spiral electrode.

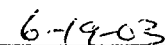
The electrode is connected to the fetal monitor using a reusable adapter cable. A disposable maternal reference electrode connection is built into the adapter cable.

Intended use: For patients requiring fetal heart rate monitoring during labor.

The Fetal Spiral Electrodes are substantially equivalent to the predicate devices because: they have the same intended uses, namely, use for monitoring fetal heart rate, and they have the same basic technological characteristics as predicate devices, namely, an electrode that attaches to the fetal scalp. They use the same or similar materials, all of which have been shown to be biocompatible and to function well in the intended application.

The safety and effectiveness are similar to existing devices as demonstrated in the laboratory testing. Biocompatibility testing shows that the materials used in the Fetal Spiral Electrode are safe for this application. Effectiveness is the same as the predicate devices. The laboratory testing verified the performance.


 Wm. Dean Wallace, M.D., Ph.D.


 Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2003

Wm. Dean Wallace, M.D., Ph.D.
President
Clinical Innovations
747 West 4170 South
MURRAY UT 84123

Re: K030691
Trade/Device Name: Fetal Spiral Electrode
Regulation Number: 21 CFR 884.2675
Regulation Name: Fetal scalp circular (spiral)
electrode and applicator
Regulatory Class: II
Product Code: 85 HGP
Dated: June 18, 2003
Received: June 20, 2003

Dear Dr. Wallace:

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); 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.

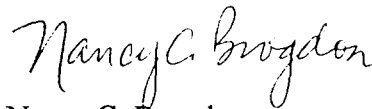
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

