FEB - 8 2005

K040788
Page 1 of 2

510(k) Summary for CALM Patterns

Prepared 03 February 2005

Submitted by:	LMS Medical Systems, Ltd. 5252 de Maisonneuve Boulevard West Suite 314 Montreal, Quebec Canada H4A 3S5
Telephone:	(514) 488-3461
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Contact Person:	Pamela J. Haswell Director, QA/RA
Device Trade Name:	**CALM Patterns**
Common Name:	Computer-based information management system for obstetrical care.
Classification:	Perinatal monitoring system and accessories
Predicate Device:	**OB TraceVue** Hewlett-Packard (K 970456)
Description of the Device:	**CALM Patterns** is a computerized method to detect, label and measure features in the fetal monitor recording. **CALM Patterns** uses fetal monitor data imported through an interface with an external source as described in a previous submission (K980719) or with a third-party clinical information system. **CALM Patterns** can function in a networked environment or as a standalone workstation.
Intended Use of the Device:	**CALM Patterns** is intended for use as an adjunct to qualified clinical decision-making during antepartum or intrapartum obstetrical monitoring at ≥36 weeks gestation to obtain annotation of the FHR for baseline, accelerations and decelerations. **WARNING:** Evaluation of FHR during labor and patient management decisions should not be based solely on CALM Patterns annotations.
Substantial Equivalence to Predicate Device:	**CALM Patterns** is substantially equivalent to the Hewlett-Packard **OB TraceVue** (currently manufactured by Philips Medical Systems). The features of **CALM Patterns** and the predicate device are compared in the table on the following page.

Feature	LMS – CALM Patterns	Hewlett-Packard - OB TraceVue*
Intended Use	To provide a standardized approach to FHR analysis through the use of computerized algorithms.	To provide a standardized approach to FHR analysis through the use of computerized algorithms.
Terminology consistent with NIHCD	Yes	Similar
Data Collection	Collects FHR and uterine activity data from maternal/fetal monitors.	Collects FHR and uterine activity data from maternal/fetal monitors.
Sample Rate	Samples FHR at a minimum of four samples per second.	Samples FHR at a minimum of four samples per second.
Annotation of the tracing	Provides for electronic annotation by the caregiver.	Provides for electronic annotation by the caregiver.
Labeling accelerations on the tracing	Yes	No
Labeling decelerations on the tracing	Yes	No. Posts a message and a time range to describe collections of feature(s).
Analysis provided and summarized in 15 minute increments	Yes	No
Displays compressed view of tracing.	Yes	No
Handling of disagreements between algorithm detected patterns and clinician opinion	User can add, modify or delete a feature annotation	Users asked to acknowledge agreement or disagreement with collections of patterns
Printing functions	Yes	Yes
Patient admission discharge transfer status	Yes	Yes

* OB TraceVue is currently manufactured by Philips Medical Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2005

Ms. Pamela Haswell
Director, Quality Assurance and Regulatory Affairs
LMS Medical Systems
5252, de Maisonneuve O. Bureau 314
Montreal, Quebec
CANADA H4A 3S5

Re: K040788
Trade/Device Name: CALM Patterns
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: 85 HGM
Dated: November 8, 2004
Received: November 9, 2004

Dear Ms. Haswell:

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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

K040788
Page 1 of

Indications for Use Form

Applicant: LMS Medical Systems, Ltd.

510(k) Number: K040788

Device Name: CALM Patterns

Indications for Use:

CALM Patterns is intended for use as an adjunct to qualified clinical decision-making during antepartum or intrapartum obstetrical monitoring at ≥36 weeks gestation to obtain annotation of the FHR for baseline, accelerations and decelerations.

WARNING: Evaluation of FHR during labor and patient management decisions should not be based solely on **CALM Patterns** annotations.

(Per 21 CFR 801.109)

__X__ Prescription Use _____ Over the Counter

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040788