DEC 2 2 2005

510(k) Summary for CALM Curve – K052715

Revised – 22 November 2005

Submitted by

LMS Medical Systems, Ltd.
5252 de Maisonneuve Boulevard West
Suite 314
Montreal, Quebec
Canada H4A 3S5

FDA facility registration number: 9615396

Telephone: (514) 488-3461
Fax: (514) 488-1880

Contact Person: Pamela J. Haswell
Director, QA/RA

Device Information

Trade Name: CALM Curve

Common Name: Computer-based labor progress monitoring system for obstetrical care.

Device Class: Perinatal monitoring systems and accessories were reviewed by the Obstetrics and Gynecology Panel and are classified in Class II per 21 CFR 884.2740.

Predicate Device Information

The predicate device for CALM Curve is the Labor Progress Monitoring module (LPM module) of LMS Medical Systems' CALM (Computer Assisted Labor Monitoring) software

K980719, clearance date 31 July 1998

Labeling and Intended Use

A draft User Guide for CALM Curve is provided as Appendix 5. The User Guide has been updated to reflect the modifications described in this submission.

A draft promotional piece for CALM Curve is provided as Appendix 6.

Intended Use

CALM Curve is intended for use as a data analysis system to assess labor progress in singleton, cephalic presentation pregnancies when the gestational age is ≥ 35 weeks. This intended use is the same as for the Labor Progress module of CALM.

The Indications for Use statement is provided as Appendix 2.

Device Description

CALM Curve is a computerized method to assess progress during labor. Its algorithms calculate the patient's progress based on user-entered values for parity, dilatation, effacement, station, contraction frequency, and epidural use. Results of these calculations are displayed graphically and as percentile values derived from comparison to a database of women with similar characteristics who delivered vaginally. CALM Curve is intended for use as a data analysis system to assess labor progress in singleton, cephalic presentation pregnancies when the gestational age is ≥ 35 weeks.

CALM Curve can function in a networked environment, as a standalone workstation, or as a web-based application. When connected to a fetal monitor, CALM Curve can use the monitor's uterine activity signal in lieu of user-entered values to calculate contraction counts.

A more detailed description of the architecture of the proposed changes is provided as Appendix 3.

Summary of Design Control Activities – Risk Analysis

The risk analysis method used to assess the impact of the modifications was a Failure Mode and Effects Analysis (FMEA). The results of that analysis are provided as Appendix 4.

Summary of Design Control Activities – Verification and Validation

The risk analysis method used to assess the impact of the modifications was a Failure Mode and Effects Analysis (FMEA). The results of that analysis are provided as Appendix 5.

Comparison to the Predicate Device

There are only three differences between CALM Curve and the LPM module of the CALM software:

- The **LPM module** runs as a module within the CALM software suite. **CALM Curve** can also be used as a stand-alone product.
- The **LPM module** derives its cumulative contraction count from fetal monitor uterine activity signals. **CALM Curve** can also accept manually-entered contraction frequency data. In obstetrical practice, clinicians routinely estimate contraction frequency without the aid of a fetal monitor. The entry of manual contraction data has the added advantage of allowing the clinician to update contraction information even when the patient is not connected to a fetal monitor, as when the patient is up and walking.
- As a part of the CALM software suite, the **LPM module** runs as a full client/server application. **CALM Curve** can also be run as a web-based product.

Statement of Substantial Equivalence to the Predicate Device

CALM Curve is substantially equivalent to the LPM module of LMS's CALM software (K980719). The features of CALM Curve and the LPM module are compared in the table below.

Feature	LPM Module of CALM	CALM Curve
Intended Use	As a system with signal analysis and display functions . . . [for] monitoring of labor progress, data analysis and display functions.*	CALM Curve is intended for use as a data analysis system to assess labor progress in singleton, cephalic presentation pregnancies when the gestational age is ≥ 35 weeks
Patient population	Singleton birth ≥35 weeks gestational age Cephalic presentation	Singleton birth ≥35 weeks gestational age Cephalic presentation
Access to the system	Client/server application	Client/server application, stand-alone PC ***OR as a web-based product***
Software application	As a module within the CALM system	As a module within the CALM system ***OR as a stand-alone application***
Algorithm	See K980719	Same algorithm
Algorithm variables	Parity, dilatation, effacement, station, epidural use, contraction count	Parity, dilatation, effacement, station, epidural use, contraction count
Contraction count	Calculated from maternal/fetal monitor uterine activity signal.	Calculated from maternal/fetal monitor uterine activity signal ***OR from data entered by the user.***
Exam data	Entered by the user	Entered by the user
Graphical display	Patient's labor progress curve and station	Patient's labor progress curve and station
Percentile display	Patient's value (in tabular display) Curve of mean and outer limits (3^{rd} / 97^{th}, 5^{th} / 95^{th}, or 10^{th} / 90^{th}) of the reference population added to graphical display	Patient's value (in tabular display) Curve of mean and outer limits (3^{rd} / 97^{th}, 5^{th} / 95^{th}, or 10^{th} / 90^{th}) of the reference population added to graphical display
Selection of reference population	Based on parity and previous delivery type (vaginal or c/section)	Based on parity and previous delivery type (vaginal or c/section)

***NOTE:** This statement is taken from the intended use statement for the cleared CALM software system, which is intended for use "as a central monitoring system with signal analysis and display functions and remote repeaters in the Perinatal clinical environment. It interfaces with standard fetal and maternal monitors and provides fetal surveillance, monitoring of labor progress, charting, reporting, and data analysis, display and archiving functions".

Declarations, Certifications, and Statements

The following declarations, certifications, and statements are provided as Appendix 4.

- **Declaration of Conformity with Design Controls**
- **510(k) Statement** for the CALM Curve
- **Certification of Truthfulness and Accuracy** of the CALM Curve described in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

Ms. Pamela Haswell
Director, QA/RA
LMS Medical Systems, Inc.
5252 de Maisonneuve West, Suite 314
Montreal, Quebec H4A 3S5
CANADA

Re: K052715
Trade/Device Name: CALM Curve
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: November 22, 2005
Received: November 23, 2005

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 (Premarket Approval), 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 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/industry/support/index.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

2.1 Indications for Use Form

Applicant: LMS Medical Systems, Inc.

510(k) Number: K052715

Device Name: **CALM Curve**

Indications for Use:

CALM Curve is intended for use as a data analysis system to assess labor progress in singleton, cephalic presentation pregnancies when the gestational age is ≥ 35 weeks.

(Per 21 CFR 801.109)

__X__ Prescription Use _____ Over the Counter

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052715