

## 510(K) SUMMARY

510(K) Number K 081984

MAR - 4 2009

- 5.1 Applicant's Name:** Trig Medical Ltd.  
Building 7, 2 Hacarmel St., P.O.B 538  
Yoqneam Ilit 20692, Israel
- 5.2 Contact Person:** Keren Shtiegman, Ph.D.  
BioMedical Strategy (2004) Ltd.  
7 Jabotinsky Street.  
Ramat Gan 52520, Israel  
Tel: +972-3- 6123281  
Fax: +972-3-6123282  
Mail: [keren@ebms.co.il](mailto:keren@ebms.co.il)
- 5.3 Date Prepared:** July 2008
- 5.4 Trade Name:** LaborPro System
- 5.5 Classification Name:** System, monitoring, for progress of labor
- 5.6 Product Code:** System, monitoring, for progress of labor, NPB
- 5.7 Device Class:** Class II
- 5.8 Regulation Number:** 884.2800
- 5.9 Panel:** Obstetrics/Gynecology
- 5.10 Primary Predicate Devices:**
1. The Computerized Labor Monitoring (CLM) System (Barnev Ltd.), cleared under K060028.
  2. USG 2000sa (UltraGuide Ltd.), cleared under K023227
- 5.12 Intended Use / Indication for Use:**

The LaborPro System is intended for monitoring the active phase of labor in women with term gestations and a singleton fetus in vertex presentation. The device intermittently assesses fetal head station, position and cervical dilation. Cervical dilation using LaborPro is assessed using position sensors during vaginal examination. The LaborPro also may be used to measure cervical length, pubic arch angle and interspinous diameter using position

sensors during vaginal examination. The LaborPro combines a magnetic tracking system including a transmitter and position sensor with an ultrasound imaging system (not included with the LaborPro). Measurements are displayed numerically and graphically as a function of time to show the progress of labor.

### **5.13 Device Description:**

The LaborPro System is comprised of the following components:

1. A magnetic based tracking system
2. A system console which integrates the tracker unit electronics and the system computer,
3. A touch screen monitor, used for display and operation.
4. LaborPro software application
5. Sensor Sleeve and reference sticker (an "off the shelf" tape and bandage adhesive).
6. An 'off the shelf' ultrasound device; not supplied with the system
7. An 'off the shelf' CardioTocoGram (CTG) monitor (optional); not supplied with the system

The LaborPro System, a minimally invasive device, assesses labor parameters intermittently by accompanying the physician during his/her routine examinations.

The LaborPro magnetic position tracking system is designed for tracking the spatial location of the sensor tip. Spatial localization of landmarks may be simply obtained by either touching external landmarks of interest with the sensor tip and/or by marking structures of interest on a ultrasound image extracted from an "off the shelf" calibrated ultrasound probe aligned with a position sensor. The spatial localization of each sensor then may allow for the assessment of certain measurements such as cervical dilatation simply by touching points within the system's working area and yielding the relative distance/angles between the touched points in a caliper-like fashion. In addition, localization of key anatomical points either by touching external landmarks with a sensor tip or marking structures of interest on an ultrasound image enable mapping of the spatial position and orientation of the pelvis and specifically the level of the pelvic inlet plane; which is used as the relative plane for the fetal head station measurement.

### **5.14 Substantial Equivalence:**

#### **Intended Use**

With regard to its intended use, the LaborPro System is substantially equivalent to the combination of its predicate devices. In similarity to the CLM predicate device, the LaborPro enables measurements of labor

progression parameters and is intended for monitoring labor. In addition, the LaborPro system is intended to measure pubic arch angle, interspinous diameter, and cervical length similar to pelvimeters and the Cervilenz Measuring Sound predicate devices respectively.

### **Technological Characteristics and Mode of Operation**

Similarly to the UltraGuide predicate device, the LaborPro System is based on an integrated “off the shelf” ultrasound and magnetic tracking system. Both devices calculate the relative spatial positions of sensors prior to analysis. Localization and relative distances and angles of landmarks of interest by the LaborPro magnetic based transmitter and sensors/receivers is similar to the CLM predicate that determines the localization and relative distances of landmarks (fetal head and cervical margins) by ultrasound based transmitters and receivers.

### **Performance Testing**

A set of software, bench and clinical testing was performed in order to demonstrate the performance and accuracy of the LaborPro System and to verify that it does not raise any new safety and effectiveness issues in comparison to its predicate devices. The testing included the following:

- Electrical safety and electromagnetic compatibility testing according to IEC 60601-1 (and amendments), and IEC 60601-1-2 (and amendment) standards.
- Software verification and validation testing was conducted to evaluate the performance of the LaborPro System and to verify that it performs according to its specifications described in the Software Requirements Specifications (SRS).
- Bench testing on a phantom.
- A clinical study was conducted to validate the accuracy of the LaborPro System against two independent experienced attending physicians and/or caregivers (gold-standard). The study results establish the accuracy of the LaborPro System in measuring labor parameters.

### **Summary**

The LaborPro System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. Based on the performance testing results, including software verification and validation process, bench and clinical testing, the analysis of the similarities and differences, Trig Medical Ltd believes that the LaborPro System is substantially equivalent to its predicates without raising new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Trig Medical Ltd.  
c/o Keren Shtiegman, Ph.D.  
BioMedical Strategy Ltd.  
7 Jabotinsky Street  
Ramat Gan 52520  
ISRAEL

MAR - 4 2009

Re: K081984  
Trade/Device Name: LaborPro System  
Regulation Number: 21 CFR §884.2800  
Regulation Name: Computerized labor monitoring system  
Regulatory Class: II  
Product Code: NPB  
Dated: February 28, 2009  
Received: March 3, 2009

Dear Dr. Shtiegman:

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 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.

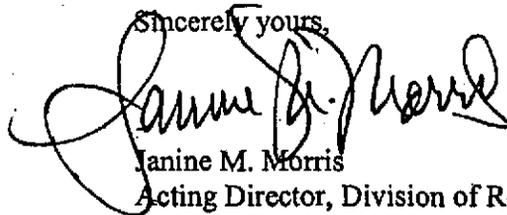
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K081984

Device Name: LaborPro System

Indications for Use:

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Prescription Use  \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

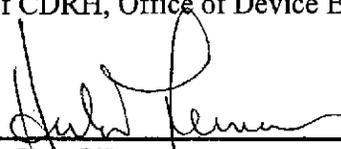
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K081984