

# **Guidance for Industry and FDA Staff**

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## **Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems**

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For questions regarding this document, please contact Colin Pollard at 240-276-4155 or by email at [colin.pollard@fda.hhs.gov](mailto:colin.pollard@fda.hhs.gov).



**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health**

**Obstetrics and Gynecological Devices Branch  
Division of Reproductive, Abdominal, and Radiological Devices  
Office of Device Evaluation**

# Preface

## Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Divisions of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Alternatively, electronic documents may be submitted to <http://www.fda.gov/dockets/ecomments>. Please identify your comments with the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

## Additional Copies

Additional copies are available from the Internet at <http://www.fda.gov/cdrh/1625.html>. You may also send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (1625) to identify the guidance you are requesting.

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## Class II Special Controls Guidance Document: Computerized Labor Monitoring Systems

*This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.*

### 1. Introduction

FDA has developed this guidance document to support the classification of computerized labor monitoring systems into class II (special controls). Computerized labor monitoring systems are intended to continuously measure cervical dilation and fetal head descent and provide a display that indicates the progress of labor. The computerized labor monitoring system includes a monitor and ultrasound transducers. Ultrasound transducers are placed on the maternal abdomen and cervix and on the fetal scalp to provide the matrix of measurements used to produce the display. This guidance is issued in conjunction with a Federal Register notice announcing the classification of computerized labor monitoring systems.

Following the effective date of the final rule classifying the device, any firm submitting a premarket notification (510(k)) for a computerized labor monitoring system will need to address the issues covered in the special control guidance. You need only show your device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## **The Least Burdensome Approach**

The issues identified in this guidance document represent those we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe there is a less burdensome way to address the issues, you should follow the procedures outlined in the document **A Suggested Approach to Resolving Least Burdensome Issues**.<sup>1</sup>

## **2. Background**

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of computerized labor monitoring systems. Therefore, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with computerized labor monitoring systems, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device. (See also 21 CFR 807.85.)

This special control guidance document identifies the classification regulation and product code for systems monitoring the progress of the active phase of labor (refer to **Section 4. Scope**). Other sections of this guidance document list the risks to health FDA has identified and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with computerized labor monitoring systems and lead to a timely premarket notification (510[k]) review and clearance. This document supplements other FDA documents regarding the content requirements of a 510(k) submission. When developing your submission, we recommend you also refer to CDRH's **Device Advice**,<sup>2</sup> 21 CFR 807.87, and **Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s**.<sup>3</sup>

As described in the guidance **The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance**,<sup>4</sup> you may submit a Traditional 510(k), or you have the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a class II special controls guidance document has been issued. If you are considering certain modifications to one of your own cleared devices, you may

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<sup>1</sup> <http://www.fda.gov/cdrh/modact/leastburdensome.html>

<sup>2</sup> <http://www.fda.gov/cdrh/devadvice/>

<sup>3</sup> <http://www.fda.gov/cdrh/ode/guidance/1567.html>

<sup>4</sup> <http://www.fda.gov/cdrh/ode/parad510.html>

lessen the regulatory burden by submitting a Special 510(k).

### **3. The Content and Format of an Abbreviated 510(k) Submission**

An abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g). We therefore recommend you include a summary report that describes:

- how this guidance document was used during the device development and testing
- the methods or tests used (briefly)
- a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document
- any additional risks specific to your device.

This section suggests information to fulfill some of the requirements of 21 CFR 807.87 and other items we recommend you include in an Abbreviated 510(k).

#### **Coversheet**

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this guidance document.

#### **Proposed Labeling**

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. Refer to **Section 14. Labeling** for specific information to be included in the labeling for devices covered by this guidance document.

#### **Summary Report**

We recommend the summary report contain the following:

##### **Description of the device and its intended use**

We recommend the description include a complete discussion of the performance specifications, and when appropriate, detailed, labeled drawings of the device. Refer to **Section 5. Device Description** for specific information we recommend you include in the description of your device. FDA also recommends you submit an “indications for use” enclosure.<sup>5</sup>

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<sup>5</sup> Refer to <http://www.fda.gov/cdrh/ode/indicate.html> for the recommended format.

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### **Description of device design requirements**

We recommend you include a brief description of the device design requirements.

### **Identification of the risk analysis method**

We recommend you identify the risk analysis method(s) you used to assess the risk profile in general, your specific device's design, and the results of this analysis. Refer to **Section 6. Risks to Health** for the risks to health FDA has identified as generally associated with the use of this device.

### **Discussion of the device characteristics**

We recommend you discuss the device characteristics that address the risks identified in this guidance document and any additional risks identified in your risk analysis.

### **Description of the performance aspects**

We recommend you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 7–13** of this guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method, but we recommend you provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.<sup>6</sup> (See also 21 CFR 820.30, Subpart C – **Design Controls for the Quality System Regulation**.)

### **Reliance on standards**

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that conformance assessment to specified acceptance criteria will be performed before the product is marketed; or
- declaration of conformity to the standard.<sup>7</sup>

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<sup>6</sup> If FDA makes a substantial equivalence determination based on acceptance criteria, we recommend the subject device be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and thus differs from the device described in the cleared 510(k), FDA recommends you apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine if marketing of the finished device requires clearance of a new 510(k).

<sup>7</sup> See **Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(k)] Submissions**,

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Because a declaration of conformity is based on results of a conformance assessment, we believe you cannot properly submit a declaration of conformity until you have completed the testing that the standard describes. For more information, please refer to section 514(c)(1)(B) of the Act and the FDA guidance **Use of Standards in Substantial Equivalence Determinations**.<sup>8</sup>

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence).

As an alternative to submitting an Abbreviated 510(k), you may submit a Traditional 510(k) that provides all the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) includes all your methods, data, acceptance criteria, and conclusions. If you are considering certain modifications to one of your own cleared devices, you may submit a Special 510(k).

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how we recommend you apply this guidance document to a premarket notification submission for a computerized labor monitoring system.

## **4. Scope**

The scope of this document is limited to the class II device described in 21 CFR 884.2800, product code, NPB.

### **21 CFR 884.2800 Computerized Labor Monitoring System**

*Identification.* A computerized labor monitoring system is a system intended to continuously measure cervical dilation and fetal head descent and provide a display that indicates the progress of labor. The computerized labor monitoring system includes a monitor and ultrasound transducers. Ultrasound transducers are placed on the maternal abdomen and cervix and on the fetal scalp to provide the matrix of measurements used to produce the display.

*Classification.* Class II (special controls). The special control is FDA's guidance document **Class II Special Controls Guidance Document Computerized Labor Monitoring Systems**. See 21 CFR 884.1(e) for the availability of this guidance document.

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<http://www.fda.gov/cdrh/ode/reqrecstand.html>.

<sup>8</sup> <http://www.fda.gov/cdrh/ode/guidance/1131.html>

## **5. Device Description**

We recommend you identify your device using the regulation and product code described in **Section 4. Scope** and include the following:

### **Device components and theory of operation**

We recommend you identify all components, system software, and accessories within the scope of the 510(k) and any collateral devices that can be connected or used with the monitor (e.g., personal computers, printers). We recommend you provide:

- energy output (e.g., for ultrasound: control setting, output parameters, beam parameters, waveform parameters)
- design characteristics (e.g., circuit diagrams, mode of transmission, acquisition cycle, signal and data processing)
- attachment devices and their validation
- software algorithm
- description of internal transducers and their angular sensitivity
- description of test and validation procedures for device energy transmission, reception, and switching modes
- description of test and validation procedures for the device's measurement accuracy.

### **Photograph or drawing of the device**

We recommend you provide a photograph or drawing of the device. We also recommend you provide a functional block diagram (including all accessories).

### **Functional performance characteristics**

We recommend you describe the functional performance characteristics of the device.

### **Patient-contacting materials**

We recommend you identify all the materials in components of the device that contact the patient.

### **Comparison to the predicate device**

We recommend you:

- identify a legally marketed predicate device
- explain how your device and the predicate are similar, with respect to

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indications for use and technological characteristics.

## **6. Risks to Health**

In the table below, FDA has identified the risks to health generally associated with the use of computerized labor monitoring systems addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as also shown in the table below. You should also conduct a risk analysis before submitting your premarket notification to identify any other risks specific to your device. We recommend the premarket notification describe the risk analysis method and include the results. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or you have identified risks additional to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

<b>Identified Risk</b>	<b>Recommended Mitigation Measures</b>
Patient Injury	Section 7. Nonclinical Analysis and Testing Section 11. Software Section 14. Clinical Information Section 15. Labeling
Electrical Hazards	Section 7. Nonclinical Analysis and Testing Section 8. Electrical Safety Section 15. Labeling
Acoustical (ultrasound) Tissue Damage	Section 7. Nonclinical Analysis and Testing Section 9. Ultrasound Safety Section 15. Labeling
Electromagnetic Interference and Electrostatic Discharge Hazards	Section 10. Electromagnetic Compatibility Section 15. Labeling
Mismanagement of Patient	Section 7. Nonclinical Analysis and Testing Section 11. Software Section 14. Clinical Information Section 15. Labeling
Adverse Tissue Reaction	Section 12. Biocompatibility
Infection	Section 13. Sterilization Information

## **7. Nonclinical Analysis and Testing**

We recommend you provide the information described below specific to computerized labor monitoring systems.

### **Ultrasound characteristics**

We recommend you provide the following:

#### *Control setting*

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- power (e.g., fixed)
- waveform (e.g., single pulse, 500 ns, 200 Vp).

#### *Output parameters*

- maximum positive acoustic pressure
- maximum negative acoustic pressure
- spatial-peak temporal-average intensity
- spatial-peak pulse-average intensity
- spatial-average temporal-average intensity
- power.

#### *Beam parameters*

- entrance beam dimension (circular)
- beam width
- z: face – max pulse pressure squared integral.

#### *Waveform parameters*

- center frequency
- pulse repetition frequency
- number of pulses per repetition
- pulse duration.

We also recommend you provide graphs of the beam and waveform characterization, including the:

- lateral and transversal beam profiles
- acoustic pulse waveform at the point of maximum acoustic pressure
- distribution of acoustic pressure along the acoustic axis.

We recommend you provide global maximum values for:

- the mechanical index
- spatial-peak temporal-average intensity
  - spatial-peak pulse-average intensity.

A tabular format is desirable.

Following IEC 60601-2-37 or equivalent methods, we recommend you measure and analyze the:

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- surface temperature rise in air and in simulated use conditions
- marking and controls and indications of parameters relevant to safety; i.e., calculation of the mechanical index and thermal indices for bone, soft tissue, and cranial bone.

### **Angular sensitivity**

We recommend you provide an analysis of the angular sensitivity of the internal transducers in the form of a polar diagram.

### **Measurement accuracy**

We recommend you assess the device's accuracy in laboratory settings on a phantom mimicking actual conditions and geometry.

#### *Accuracy of cervical dilation*

We recommend you measure the device readings in the range of 3 cm to 10 cm, and assess the accuracy in the measurement of cervical dilation by analyzing the following parameters:

- average difference between the device readings and the actual values;
- standard deviation between the device readings and the actual values; and
- maximum difference between the device readings and the actual values.

#### *Accuracy of head station*

We recommend you measure the device readings in the range of -4 cm to +4 cm, and assess the accuracy in the measurement of cervical dilation by analyzing the:

- average difference between the device readings and the actual values;
- standard deviation between the device readings and the actual values; and
- maximum difference between the device readings and the actual values.

If your device is labeled to be used with other labor monitoring systems, we recommend you validate the compatibility of your system to operate with the other systems.

### **Mechanical Characteristics**

We recommend that you provide:

- a mechanical description of the transducers and cabling, including tensile testing of the transducer, cable, and interface;
- a description of the transducer-patient attachment mechanism, including breakage and failure analysis;
- a description of all moving system components (e.g., cables, connectors, transducers, monitor) and associated breakage and failure analyses for each

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component; and

- the results of functional testing of the moving system components under worst case mechanical stresses.

## **8. Electrical Safety**

We recommend you address the electrical equipment safety; for example, the electrical safety of your device following one or more of the standards below or by equivalent methods.

- International Electrotechnical Commission (IEC) 60601-1 Medical Electrical Equipment – Part I: General Requirements for Safety
- American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) ES-1 Safe current limits for electromedical apparatus (electrical safety only)
- Underwriters Laboratory (UL) 2601-1 Amendment 1 Medical Electrical Equipment: General Requirements for Safety

## **9. Ultrasound Safety**

We recommend you address the safety of ultrasound by following the guidance document **Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers**.<sup>9</sup> The sections on Track 1 devices; that is, those devices that do not incorporate a real-time acoustic output display as defined in IEC 60601-2-7 are applicable.

The Obstetrics and Gynecology Devices Branch is available to answer any questions you may have about which standards are appropriate for your device's features and design.

## **10. Electromagnetic Compatibility**

Electromagnetic compatibility (EMC) encompasses both emissions (interference with other electronic devices) and immunity (interference with device performance created by emissions from other electronic devices.) We recommend you evaluate the EMC of your device as discussed below.

### **Emissions**

FDA recommends EMC testing demonstrate the device will not adversely interfere with the performance of other electronic equipment, including:

- emergency radio services

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<sup>9</sup> <http://www.fda.gov/cdrh/ode/ulstran.pdf>

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- diagnostic devices
- active implantable devices; e.g., pacemakers, defibrillators.

We recommend testing include the measurement of electromagnetic and conducted emissions.

#### **Immunity**

FDA recommends EMC testing also demonstrate the device will perform as expected in the presence of other electrical and electronic devices or other sources of electromagnetic disturbance in the intended environment of use (immunity). The device should operate in an acceptable manner during and after exposure to various forms of electromagnetic disturbance. FDA recommends testing include exposure to:

- electrostatic discharge (ESD)
- radiated electromagnetic fields
- electrical fast transients and bursts
- surges
- conducted electromagnetic energy
- voltage dips, short interruptions, and voltage variations on power supply input lines
- low-frequency magnetic fields.

We recommend you address the EMC of your device by following the standard listed below or by equivalent methods.

- IEC 60601-1-2 Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests

## **11. Software**

We recommend that you submit the information for software-controlled devices described in **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**.<sup>10</sup> The kind of information we recommend you submit is determined by the “level of concern,” which is related to the risks associated with software failure. The level of concern for a device may be minor, moderate, or major. The level of concern for computerized labor monitoring systems is likely to be “moderate level of concern.” This is because failure to obtain accurate information may result in more frequent vaginal examinations that can lead to chorioamnionitis or patient mismanagement.

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<sup>10</sup> <http://www.fda.gov/cdrh/ode/guidance/337.html>

## 12. Biocompatibility

We recommend you evaluate the biocompatibility of the materials in patient contacting parts as described in the guidance, **Use of International Standard Organization (ISO) Standard ISO 10933, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing**.<sup>11</sup> We recommend you select biocompatibility tests appropriate for limited duration (less than 24 hours) and for surface devices in contact with breached or compromised surfaces. If identical materials and identical material processing are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of providing biocompatibility testing.

## 13. Sterilization Information

For devices marketed as sterile, FDA recommends that you provide sterilization information in accordance with the **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**.<sup>12</sup> You should sterilize the device to a sterility assurance level (SAL) of  $1 \times 10^{-6}$  using a sterilization cycle that has been validated in accordance with 21 CFR Part 820 Quality System Regulation.

## 14. Clinical Information

In accordance with the Act, FDA will rely upon well-designed bench and clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While generally, clinical studies will not be needed for most computerized labor monitoring systems, FDA recommends you collect clinical data for computerized labor monitoring systems with any one of the following:

- design dissimilar from design previously cleared under a premarket notification
- new technology; i.e., technology different from that used in legally marketed computerized labor monitoring systems
- indications for use dissimilar from computerized labor monitoring systems of the same type.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale.

If we recommend a clinical study, we recommend you design your study to demonstrate the substantial equivalence (such as equivalence of the given results to two experienced caregivers) of the device when used as described in the “indications for use” statement. When supported by an adequate scientific rationale, alternatives such as reliance on the literature or use of meta-analysis may be appropriate. We have outlined our

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<sup>11</sup> <http://www.fda.gov/cdrh/g951.html>

<sup>12</sup> <http://www.fda.gov/cdrh/ode/guidance/361.html>

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recommendations for each below.

For statistical purposes, we recommend the study hypothesis frame the research question in terms of equivalence, non-inferiority, or superiority to the performance of legally marketed predicate devices of this type, or to standard of care physician measurements. We also recommend you consult a statistician familiar with medical device studies.

### **Statistical reporting in your premarket notification of clinical study results**

If you conducted a clinical study, we recommend you define the:

- primary clinical effectiveness endpoints
- safety endpoints
- null and alternative hypotheses (in both words and mathematical form)
- method for estimating the difference between system measurements and clinical (manual) measurements. The approach should estimate (i) mean difference (bias) and (ii) mean *absolute* difference (absolute bias) and incorporate results from at least two independent experienced attending physicians or caregivers.
- sample sizes.

We also recommend you describe the:

- length of follow-up
- masking and randomization procedures
- statistical methods used to analyze the clinical data.

If a multi-center study is employed, we recommend that no less than 50 percent of studies be in the United States. We also recommend you discuss the primary summary statistics (ratio difference, relative risk, odds ratio, or others, such as the means).

### **Reporting results from journal articles**

If you report results from journal articles, we recommend you evaluate the consistency of study designs among various studies, such as:

- randomization procedure
- success and failure criteria
- masking
- types of study design (e.g., prospective, retrospective, cross-sectional)
- duration of patient follow-up
- patient demographics and clinically important patient covariates (if known)
- patient accountability

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- data quality (e.g., who obtained and audited data, blinding, subject confidentiality)
- types of clinical centers
- patient inclusion and exclusion criteria
- physician experience
- any other relevant factors.

We also recommend you evaluate any potential publication bias.

We recommend you prepare a homogeneity test in summary statistics and provide a statistical justification for pooling multi-center studies from the literature.

### **Reporting meta-analyses (for both original clinical studies and journal articles)**

If summary data from individual studies are available, we recommend for each center or each study and for the selected summary statistics that you graphically display the:

- point estimate
- 95 percent confidence interval
- width of the 95 percent confidence interval.
- sample proportion by device and control groups.

We also recommend you calculate the appropriately pooled average estimate of summary statistics and the associated 95 percent confidence interval from various appropriately selected studies.

If a clinical study is needed to demonstrate substantial equivalence, the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. FDA generally believes a computerized labor monitoring system addressed by this guidance document is a non-significant risk device if information from the monitor is not being used to manage the patient during the course of the study. Therefore, the study is subject to the abbreviated requirements of 21 CFR 812.2(b).<sup>13</sup> In addition to the requirement of section 21 CFR 812.2(b), sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

## **15. Labeling**

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions will assist you in

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<sup>13</sup> <http://www.fda.gov/oc/ohrt/irbs/devices.html#risk> (Significant Risk and Nonsignificant Risk Medical Device Studies)

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preparing labeling that satisfies the requirements of 21 CFR Part 801.<sup>14</sup>

### **Directions for use**

We recommend submitting clear and concise instructions that delineate the technological features of the specific device and how the device is to be used. We also recommend that the instructions describe the procedure for measuring cervix dilation and fetal head station.

### **Warnings**

We recommend that the warnings section of your operator manual address the need for vaginal examination in addition to monitoring to prevent mismanagement of the patient. The following is an example:

The device is monitoring equipment only and is not to be relied upon to make clinical decisions without a vaginal examination prior to decision-making.

In addition, the warnings should address adequate professional training and proper device use, for example:

The device provides selected clinical parameters for evaluating the progress of labor. The device is not a substitute for observation and evaluation of the mother and fetus by a qualified caregiver who is responsible for making clinical management decisions. The device is intended for use by professionals who are expected to know the medical procedures, practices, and terminology required to monitor women in labor and who are trained in all aspects of the system use.

We also recommend warnings that address the risk of patient injury, for example:

Do not leave internal transducers in place during vacuum extraction, forceps delivery, or Cesarean delivery. Doing so may cause patient injury.

### **Indications for use**

FDA recommends your indications for use address:

- how the device functions
- what the device measures and displays
- when use of the device is indicated.

An example:

The computerized labor monitoring system is intended for monitoring the active

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<sup>14</sup> Although the final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

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phase of labor in women with term pregnancies, vertex presentation, and ruptured membranes. It is intended to be placed when cervical dilation is between 3 cm and 7 cm. The device continuously measures cervical dilation and fetal head station with ultrasound transducers attached to the maternal abdomen and cervix and to the fetal scalp. These measurements are displayed numerically and graphically as a function of time to show the progress of labor.