Mobile Medical Devices
Final Project Assignment
Submittal of the MMDA 510(k)

[Base upon
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142651.htm]

- Introduction
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Introduction

The 510(k) should provide sufficient detail for MMDA_FDA (or in this case your instructors) to be able to determine that the device is substantially equivalent (SE) to another similar legally marketed device(s).Our version of the 510(k) should not exceed 10 pages. For any device, the 510(k) is formatted essentially the same way and contains the same basic information (required elements).

This introduction is an overview to give you the experience of preparing a medical device for the marketplace in the United States. The objective of this process is to obtain marketing clearance. To facilitate MMDA_FDA (or in this case your instructors) review of the data, analysis, and conclusions in the application, you acting as the manufacturer should check for the:

- logical presentation of the data;
- scientific soundness of the test and data analysis;
- relevance of the test program to the device and the intended use; and
- completeness of the summary report of the tests or studies.

A description of the tests and the results obtained are essential. Reasonable and sufficient details of all test procedures and results should be submitted to the MMDA_FDA.

Important Note: In order to address the required elements, you will need the following information to assure that your 510(k) is complete. If you do not have this information, you should obtain it prior to submitting via email to your instructors.

1. Classification of your device – See Appendix A.
2. Predicate device(s) – See Appendix B.
3. Final draft labeling of your product
4. Specifications including engineering drawings, photos, etc.
5. Performance data such as bench, animal, or clinical testing (if applicable)
6. Sterilization information (if applicable)
7. Guidance document(s) specific to your device type, if it exists

It is not a requirement that you organize your MMDA_510(k) into the following labeled sections; you may make modifications in order to meet the specific needs of your device. The following is a brief discussion of the required elements.

General Information

Medical Device User Fee Cover Sheet (Form FDA 3601) – see MDUFMA Cover Sheet 3601.pdf on Box. The first page of a 510(k) should be a printed copy of the Medical Device User Fee Cover Sheet (Form FDA 3601). The Medical Device User Fee Cover Sheet and instructions are available online.
Cover Letter – You may use a cover letter to provide the information about your:

1. Submission date (month/day/year) and labeled as "510(k) Submission." The submission must be clearly identified as a 510(k) submission for accurate processing by the MMDA_FDA.
2. Submitter name(s) and e-mail address. Only your team is allowed to complete your report.
3. Your MMDA team number.
4. The common name of the device. The common name is the name of the device as it is commonly known e.g., syringe, hip implant.
5. The trade name (proprietary name) including the model number(s) of the device. The trade name is the name under which the device will be marketed.
6. The classification name for the device and the class in which the device has been placed. The classification name is the generic category the device has been placed. Reference the classification regulation and the three letter product code. If you determine that the device has not been classified, include a statement of that fact. For example, "To my knowledge FDA has not classified this device. The product code of xxx has been assigned to this device in the Classification Database." If known, include the appropriate classification panel such as anesthesiology, orthopedic, etc. Accessories to classified devices take on the same classification as the "parent" device. An accessory such as software that accepts input from multiple devices usually takes on the classification of the "parent" device with the highest risk, i.e., class.
7. The reason for the 510(k). Since this is a new device (i.e., you have never marketed the device in the U.S.), you must describe it in detail so the MMDA_FDA understands it. State if the device is an accessory or finished

component. A finished component is sold to the end user while the end user cannot use an unfinished component until further manufacturing steps occur, such as sterilization. Finished components are packaged and labeled for use and are for general sale while unfinished components are usually only sold to other device manufacturers for inclusion in another medical device.

8. Identification of the legally marketed device (predicate) to which you claim Substantial Equivalence. Substantial equivalence is the initial step, establishing medical, functional, and operational differences in the new product compared to a conventional counterpart—differences are analyzed and evaluated, and further testing may be conducted, leading to a final safety assessment. If known, provide the 510(k) number for the predicate device, trade name and product code.
9. If applicable, include the registration number, name and address of each facility used to manufacture the finished device including contract sterilizers and packagers. The manufacturing process at each facility must be essentially the same and produce the same device as described in your 510(k) submission or state the differences.
10. Compliance with any special controls [section 513(b) of the Food, Drug, and Cosmetic (FD&C) Act,] FDA mandatory performance standards (section 514 of the FD&C Act), standards under the Radiation Control for Health and Safety Act (RCHSA), or voluntary consensus standards. If no special controls, mandatory performance standards or radiation device standards exist for your product state, "No applicable mandatory performance standards or special controls exist for this device." If you are claiming substantial equivalence to one or more devices that meet a given standard, then your device should meet the same standard.
    - Any required special controls for a device are provided in the regulation for the device
    - Only one MMDA_FDA mandatory performance standard exists for medical devices under section 514. Manufacturers of electrode lead wires and patient cables must conform to the standard.
    - If your device emits ionizing, non-ionizing, sonic, or light radiation, performance standards may exist for the radiation emitting device under RCHSA.

Table of Contents

Prepare a Table of Contents your 510(k). The table of contents should list each required item with page numbers, including a list of attachments and appendices. It is usually easier to number pages by section, e.g. 1.1, 1.2 (or use dashes, 1-1), 2.2, 2.3, etc. If additional pages need to be inserted into a section, it is easier to renumber that section than having to renumber all the pages that follow the inserted material if you used sequential numbering.

510(k) Acceptance Checklist
The 510(k) Acceptance Checklist is used to determine whether the 510(k) meets a minimum threshold of acceptability and should be accepted for substantive review. It is helpful to attach the 510(k) Acceptance Checklist following the Table of Contents. It should include page numbers where each of the elements in the 510(k) can be found. This will allow the FDA to easily find each required element. Second, by writing page numbers on the checklist, the 510(k) submitter may better ensure that the 510(k) is complete. The 510(k) may not be accepted for review if any of the required elements are not provided. For an Acceptance Checklist for 510(k)s see the file 1793.pdf on trunk.

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Statement of Indications for Use

Prepare a Statement of Indications for Use as a separate page. The statement should include specific indications, clinical settings, define the target population, anatomical sites, etc. This statement must be consistent with your labeling, advertising and instructions for use.

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510(k) Summary or Statement

Prepare either a 510(k) Summary. The Summary is required for all 510(k)s whether the device is Class I, II, or III. A 510(k) Summary is a summary of information upon which you based your claim of substantial equivalence.

A 510(k) Summary must be included in your 510(k) submission in order for MMDA_FDA to begin its scientific review of the 510(k) submission.

Please ensure that you submit a 510(k) Summary that meets the content and format regulatory requirements.

510(k) Summary
The conditions for a 510(k) summary must be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. The 510(k) summary must contain the information described below.

[ ]	The summary should be in a separate section of the submission. It should begin on a new page and end on a page not shared with any other part of the 510(k) submission.
[ ]	The summary contains on the first page, preferably on your letterhead paper, the 510(k) team member's name and date the summary was prepared.
[ ]	The summary includes the name of the device, including the trade or proprietary name, if applicable, the common or usual name, and the classification name, if known.

Example:	
•	Trade name - DRAG@N LATEX EXAMINATION GLOVES
•	Common name - exam gloves
•	Classification name - patient examination glove
[ ]	The summary identifies the legally marketed device to which your team is claiming equivalence.
[ ]	The summary includes a description of the device such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.
[ ]	The summary provides the intended use of the device including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the predicate device, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled.
[ ]	The 510(k) summary contains a summary of the technological characteristics of your device compared to the predicate device. If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device, a summary of the technological characteristics of the new device in comparison to those of the predicate device should be included. If your device has different technological characteristics from the predicate device, provide a summary of how the technological characteristics of your device compare to the predicate device.
[ ]	If the determination of substantial equivalence is also based on an assessment of non-clinical performance data, the summary includes a brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence and how their results support a determination of substantial equivalence.
[ ]	If the determination of substantial equivalence is also based on an assessment of clinical performance data, the summary includes a brief discussion of clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence and how their results support a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any

	other information from the clinical testing relevant to a determination of substantial equivalence. Please note: Clinical data is not needed for most devices cleared by the 510(k) process.
[ ]	The summary includes the conclusions drawn from the nonclinical and clinical tests (discussed above) that demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.
[ ]	The summary includes any other information reasonably deemed necessary by MMDA_FDA. Such requests will be made directly to the applicant by MMDA_FDA or the requirements will be published in guidance documents. Additional information requested by MMDA_FDA during review of the 510(k) may include additional safety and effectiveness information that may necessitate an update of your summary.
[ ]	Please make sure you have included all of the information listed above and verify that the following criteria have been met.
•	The summary includes only information that is also covered in the body of the 510(k).
•	The summary does not contain any puffery or unsubstantiated labeling claims.
•	The summary does not contain any raw data, i.e., contains only summary data.
•	The summary does not contain any trade secret or confidential commercial information.
•	The summary does not contain any patient identification information.
•	The summary does not exceed 5 to 7 pages written and 1 to 3 pages for figures, charts, images, and other non-written information.
•	The due date is no later than prior to making your final presentation.

Truthful and Accurate Statement

All 510(k) submitters must include a statement certifying that all information submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. The statement may be included in the 510(k) Cover Letter or may be on a separate page identified in the table of contents.

Proposed Labeling

Prepare a labeling section to include copies of all proposed labels, labeling, package inserts, service manuals, instructions for use, advertising and/or promotional materials. The directions for use should include a specific intended use statement and any warnings, contraindications, or limitations. The material does not have to be glossy, finished labeling or promotional material, draft is sufficient. However, the

labeling you submit should be final draft. Copies of labeling for the predicate device(s) is recommended. Labeling guidance is provided below:
Labeling – See Appendix C for a summary of the MMDA_FDA Blue Book Memorandum for Device Labeling Guidance

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Specifications

This section should include both a narrative description of the device and a physical or technical description.

The narrative description of the "new" device should include the indications for use, principles of operation, power source, composition and other information necessary to understand the device. If the 510(k) is for an accessory or component sold to an end-user, describe a typical device with which the accessory or component will be used. List all variations of the "new" device, which you intend to market.
The physical description of the "new" device may include labeled diagrams, photographs or pictures, engineering drawings, schematics, etc. These may include all internal and external, assembled and unassembled, interchangeable, etc., parts of the device and should address their name and function. In addition, the description should include the length, width, height, diameter, weight, etc., of the device and identify any parts, which are intended for single use.
Device specific guidance documents, if available, usually provide extensive information on the level of detail, which should be included in the specifications list.

Substantial Equivalence Comparison

The device specifications are the basis for the comparison of features between the new and the legally marketed device to which compared (predicate device). Substantial equivalence is to be established with respect, but not limited to, intended use, design, energy used/delivered, materials, performance, safety, effectiveness, labeling and other applicable characteristics, such as sterility. You should include a comparison table AND discussion of the similarities and differences of your device compared to one or more predicate devices to which you are claiming equivalency.

The equivalence information should be provided in a clear and comprehensive format. A chart, table or other side-by-side comparisons is a systematic way to compare the devices. Side-by-side comparisons, wherever possible, are desirable. For some devices a simple table of comparisons, which lists characteristics, will be sufficient to establish equivalence. Often, information is necessary to resolve questions of safety or effectiveness, especially where differences in technologies exists between the predicate and the new device. It must be shown that technological differences do not adversely affect safety and effectiveness.

Supporting information can be obtained from bench testing, animal studies or clinical studies (information gathered from medical literature) or clinical trials. State whether the legally marketed device for comparison is a pre-amendments device, or a device, which has been granted marketing clearance by MMDA_FDA following the submission of a 510(k). Provide the 510(k) document control number (i.e., K followed by 6 digits) for the device to which you are claiming equivalency, if known.

The comparison table should identify relevant similarities and differences in areas such as:

- intended use
- indications for use
- target population
- anatomical site
- where used (hospital, home, ambulance, etc)
- energy used and/or delivered
- human factors
- design
- performance
- standards met
- materials
- biocompatibility
- compatibility with the environment and other devices
- sterility
- electrical safety
- mechanical safety
- chemical safety
- thermal safety
- radiation safety

The discussion of the similarities and differences should elaborate on the similarities identified in the table of comparisons and justify the differences with supporting rationale and/or data. It is recommended to submit labeling for the device to which you are claiming equivalency.

Performance

Most 510(k)s will include some type of performance data. The extent of performance data will depend on the complexity of the device and its intended use and indications. Performance data should be provided to help demonstrate SE of your device to one or more legally marketed devices (predicate device). The data may include test results from engineering, bench, design verification, human factors, and animal testing, and clinical studies and clinical trials. Tests should be conducted on all sizes and models of the device in a manner as similar as possible to how the device will be used. The results of testing and methodology / parameters used for

testing should be included. Information on the extent of performance testing as well as the extent of specification documentation can be found in the product specific guidance documents, if one has been prepared for your device by MMDA_FDA. Search the Guidance Document page to determine if guidance documents are available for your type of device. For more information on when MMDA_FDA may request clinical performance data to support a substantial equivalence determination.

Additional requirements

Additional information may be required under certain conditions, such as if your device contains software or a color additive, is labeled sterile, or emits electronic radiation. See "Special Considerations" under Device Advice Premarket Notification 510(k) for additional guidance.

Appendix A – Device Classification

The three device classes are:
(1) There are established the following classes of devices intended for human use:CLASS I, GENERAL CONTROLS.
(i) A device for which the controls . . . are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it
(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and
(II) does not present a potential unreasonable risk of illness or injury, is to be regulated by the controls referred to in clause (i).

CLASS II, SPECIAL CONTROLS.
A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance.

CLASS III, PREMARKET APPROVAL.
A device which because:
(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in CLASS 2 would provide reasonable assurance of its safety and effectiveness, and
(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or
(II) presents a potential unreasonable risk of illness or injury, is to be subject to Premarket approval to provide reasonable assurance of its safety and effectiveness.

Appendix B – Predicate Device(s)

Information which can be useful to find a predicate device includes:

- names of similar devices - traded name under which the device is marketed;
- manufacturer(s) of the similar device(s);
- marketing status, i.e., preamendments or postamendments device;
- 510(k) numbers for postamendments devices;
- classification information, i.e., product codes, classifying regulations, etc., for your device.

Once you have found the classification of your device, you should begin your search in the 510(k) database.

You may have to try several ways of searching the database. It is usually best to complete only one box in the online search form per search. The search engine searches for an exact match of text. Therefore, one descriptive word in the "device name" box is recommended.

Preamendment Devices or Postamendment Devices depend upon whether or not the devices were introduced into interstate commerce for commercial distribution. Postamendment devices are automatically classified into Class III.Those devices remain in Class III and require premarket approval, unless and until the device is reclassified into Class I or II.

Appendix C – Device Labeling Guidance

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I. Definitions

Label: A "label" is a display of written, printed or graphic matter upon the immediate container of any article

Labeling: "Labeling" includes all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Intended Uses: The term "intended uses" refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by their expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such representatives. It may be shown by the offering or the using of the device, with the knowledge of such persons or their representatives, for a purpose for which it is neither labeled nor advertised.

Directions for Use: the term "Directions for use" provides directions under which the practitioner or layman (e.g., patient or unlicensed healthcare provider), as appropriate, can use the device safely and for the purposes for which it is intended. Directions for use also include indications for use and appropriate contraindications, warnings, precautions and adverse reaction information. Directions for use requirements applicable to prescription and over-the-counter devices .

II. Safety and Effectiveness Considerations

In determining the safety and effectiveness of a device for its intended use, the following factors are to be considered and addressed in the device's labeling by the inclusion of appropriate information:

The persons for whose use the device is represented or intended - The conditions of use for the device, including conditions of use prescribed, recommended or suggested in the labeling or advertising of the device, and other intended conditions of use; The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; The reliability of the device; and, Other relevant factors.

III. Indications for Use

General Statement of Indications for Use

The general statement of the "Indications for Use" identifies the target population in a significant portion of which sufficient valid scientific evidence has demonstrated that the device as labeled will provide clinically significant results and at the same time does not present an unreasonable risk of illness or injury associated with the use of the device. As appropriate, the labeling should state that the device (trade name) is "indicated "or "intended for use"

(1) in the treatment, mitigation, prevention or diagnosis of a recognized disease or condition or an important manifestation of a disease or condition; and/or,
(2) in the relief or mitigation of symptoms associated with a disease or condition; and/or,(3)as an aid or adjunct to a mode of therapy or diagnosis.

Additional Information

When indicated or intended for use in selected subgroups of a population with a disease, symptom, or syndrome, the labeling should:

(1) describe the available evidence and state the limitations of usefulness of the device;
(2) identify specific tests needed for the selection or monitoring of the patients;
(3) if available, provide information on the approximate kind, degree and duration of improvement to be anticipated; and
(4) if relevant, include information regarding the recommended intervals between device use, the usual duration of treatment, or any modifications of such.

When safety considerations are such that the device should be reserved or restricted for use in certain situations (e.g., cases not responsive to other devices, surgical procedures or drugs), this information shall be stated. When there are specific conditions that should be met before the device is used on a long-term basis (e.g., demonstration of responsiveness to the device in a short term trial), the labeling should identify the conditions or, if the indications for long-term use are different from those for short-term use, the labeling shall identify the specific indications for each use.

When there is a common belief that the device may be effective for a certain use or there is a common use of the device for a condition but the preponderance of evidence related to the use or condition demonstrates that the device is ineffective, FDA may require that the labeling state that there is a lack of evidence that the device is effective for that use or condition.

IV. Contraindications

This section describes situations in which the device should not be used because the risk of use clearly outweighs any possible benefit. Examples that may, but not always, contraindicate the use of a device include:

Hypersensitivity to an ingredient of a permanently implanted device; Substantial risk of being harmed because of age, sex, concomitant therapy, disease state or other condition; or, Continued use in the face of an unacceptably hazardous adverse reaction.

Known hazards and not theoretical possibilities are to be listed, e.g., if hypersensitivity to an ingredient in the device has not been demonstrated, it should not be listed as a contraindication. The "Contraindications" section shall immediately follow the "Indications for Use" section of the labeling. If no contraindications are known, this section of the labeling should state "None known."

V. Warnings

Describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should betaken if they occur. Include an appropriate warning if there is reasonable evidence of an association of a serious hazard with the use of the device. A causal relationship need not have been proved. A warning is appropriate when the device is commonly used for a disease or condition for which there is a lack of valid scientific evidence of effectiveness for that disease or condition and such usage is associated with a serious risk or hazard.

VI.Precautions

Include information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device, for example:- Indicate or emphasize any need for protective wear during use. Identify any laboratory tests or other evaluations that may be helpful in following the patient's response or in identifying adverse reactions and, if appropriate, specify the frequency of such tests or evaluations before, during and after use of the device.

The "Precautions" section of the labeling includes precautionary statements not appropriate for inclusion under other sections of the labeling. Additional guidance regarding precautions will be found in the "Special Patient Populations" section below.

VII.Special Patient Populations

Limitations on the usage of a device may be necessary for various reasons including lack of long-term safety and effectiveness data, lack of safety and effectiveness data for specific patient populations (e.g., pregnant women), growth processes still occurring in the body, and anatomical or physiological limitations on the effectiveness of the device.

If the safety and effectiveness of the device for use in specific patient populations have not been established on the basis of valid scientific evidence, the "Indications

for Use section shall specifically identify the persons for whose use the device is indicated and the "Precautions" section shall include the following statement:

"Safety and effectiveness in (e.g., pregnant women, children under the age of ..., etc.) have not been established."

If use of the device in a certain patient population is associated with a specific hazard, the hazard shall be described in the "Precautions" section or, if appropriate, the hazard shall be stated in the "Warnings" or "Contraindications" section and the "Precautions" section of the labeling shall refer to it, e.g., "See 'Warnings' section for information on....."

VIII .Adverse Reactions

An adverse reaction is an undesirable effect, reasonably associated with the use of the device, that may occur as part of the effect of the device or may be unpredictable in its occurrence.

This section includes all adverse reactions reasonably associated with the use of the device, including those mentioned in the "Contraindications", "Warnings" and "Precautions" sections of the labeling. The listing of the adverse reactions should be followed, if appropriate, by statements directing the reader to other sections of the labeling for additional information regarding these adverse reactions and any steps that' should be taken.

Adverse reactions should be listed in descending order according o their clinical significance as determined by their severity and frequency. Provide frequency data from adequately reported clinical studies when the data is not well known to the device user (practitioner and/or patient) and/or when needed in deciding between the use of the device and an alternative procedure or approach.

IX. Prescription Devices

A prescription device is, by definition under 21 CFR 801.109, a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of the device, and hence for which "adequate directions for use" (21 CFR 801.5) cannot be prepared.

A prescription device, other than surgical instruments, is misbranded if its label does not bear:

(1)the statement, "Caution: Federal law restricts this device to sale by or on the order of a", the blank to be filled with the word "physician", "dentist", or with the descriptive designation of any other practitioners licensed by the law of the State in which that person practices to use or order the use of the device; and

(2)the method of application or use of the device.

A prescription device is misbranded if its labeling does not bear:

(1) information for use including indications, effects, routes, methods, frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes forwhich it is advertised or represented, with the exceptions that

(a) such information may be omitted from the dispensing package if, but only if, the directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device and the FDA Commissioner is requested to offer an opinion on a written proposal stating reasonable grounds to omit such information from the dispensing package;
(b) such information will not be required on so called reminder-piece labeling which calls attention to the name of the device but does not include indications or other use information; and
(2)the date of the issuance or the latest revision of the labeling, except for labels and cartons, that bears directions for the use of the device.

X. Restricted Device

Under the authority of the Federal Food, Drug, and Cosmetic Act (the act), the approval order for a premarket approval application (PMA) may require, as a condition of approval, that the sale, distribution and use of the device be restricted but only to the extent permitted of the act. Per the act, MMDA_FDA may require that a device be restricted to sale, distribution and use only upon the written or oral authorization of a practitioner licensed by law to administer or use such devices(i.e., prescription device) or upon such other conditions that MMDA_FDA may prescribe. Such a requirement must be based upon a determination by MMDA_FDA that, because of the device's potentiality or harmful effect or the collateral measures necessary to its use, there cannot otherwise be reasonable assurance of its safety and effectiveness. If the device is restricted to use by persons with specific training or experience in its use or by persons for use in certain facilities, MMDA_FDA must determine that such a restriction is required for the safe and effective use of the device. A person cannot be excluded from using a device, however, solely because that person does not have the training and experience to make him/her eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board.

When the sale, distribution and use of a device are restricted in a PMA approval order or by regulation under the act, the label must include appropriate statements of the restrictions imposed by MMDA_FDA (e.g., restrictions on the sale, distribution

and use of the device or restrictions on the use of the device to persons with specific training or experience in its use or to persons for use in certain facilities). The label shall bear the statement, "Caution: Federal law restricts this device to sale, distribution and use by or on the order of a ", the blank to be filled with the word "physician", "dentist", or with the descriptive designation of any other practitioners licensed by the law of the State in which that person practices to use or order the use of the device and, if applicable, followed by a descriptive phrase of the training or experience required (e.g., "trained and/or experienced in ",the blank to be filled with, as appropriate, "the use of this device" or specified therapeutic or diagnostic procedures) and/or the facilities to which use is restricted.

In accordance with the provisions of the act, advertisements and other descriptive printed material issued by the manufacturer, packer or distributor with respect to a restricted device must include the following among other things:
(1)a true statement of the device's established name(common or usual name unless there is an official name designated by MMDA_FDA or recognized in an official compendium), printed prominently and in type at least half as large as that for any trade or brand name for the device; and
(2)a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications.

Except in extraordinary circumstances, FDA cannot require prior approval of the content of any advertisement except in the case of any printed matter which FDA determines to be labeling as defined in section 201(m) of the act.

XI. Patient Information Labeling

Patient information labeling includes labeling directed to the patient as well as family members and others who administer home use devices to patients, e.g., care providers who oversee the use of infant apnea monitors and nebulizers. In determining whether patient information labeling is appropriate for a prescription device, the following factors, among others, should be considered:

-Should the patient be aware of alternative(s) to the use of the device if a choice is available?

Are substantial risks or discomforts associated with the use of the device?

Is the need for strict patient adherence to a specific treatment regimen required?

Does substantial public or professional controversy exist about the device and its related procedures?

Patient information labeling shall include the indications for use and relevant contraindications, warnings, precautions and adverse reactions using terminology well known and understood by the average layman. Technical terms should be kept

to a minimum and should be defined when necessary. If applicable, directions to ensure safe and effective use of the device by the patient shall be included. Patient information labeling, if possible, should not exceed the seventh grade reading comprehension level.

The following sources may provide useful information regarding the information to be included as well as the terminology to be used in patient information labeling:

1.U.S.P. Dispensing Information, Volume II, Advice for the Patient, Drug information in Lay Language
2.American Medical Association Drug Evaluations

XII. Disclaimer of Liability

Inclusion in the labeling of a disclaimer regarding the safety and effectiveness of the device for its indicated or intended use is to be avoided. Instead, labeling and promotional material may include an objective and accurate representation of the clinical experience with the device whereby the practitioner and patient are made aware not to expect a completely safe and effective outcome with the use of the device in all cases.

Inclusion of disclaimers of liability for any medical expenses or any direct or consequential damages resulting from or caused by any defect, failure or malfunction of the device will not inhibit MMDA_FDA in imposing the notification and other remedies (repair, replacement or refund) provisions of the act. The provisions may be imposed whenever MMDA_FDA determines that:

(1)The device presents an unreasonable risk of substantial harm to the public health;

(2)There are reasonable grounds to believe that the device was not properly designed and manufactured within the state of the art; or

(3)There are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than the manufacturer, importer, distributor or retailer of the device to exercise due care in the ... use of the device.

XIII. Misbranding

Pertinent provisions in the law and implementing regulations related to medical device labeling and enforced by MMDA_FDA appear below.It is important that these provisions be kept in mind both in the development of labeling by the device industry and in the labeling review.

The Federal Food, Drug, and Cosmetic Act (the act) provides that a device shall be deemed misbranded if:

(1) Its labeling is false or misleading in any particular.

(2) The label does not bear the name and place of business of the manufacturer, packer or distributor and an accurate statement of the quantity of contents in terms of weight, measure or numerical count.

(3) Any required word, statement or other information to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(4) Labeling does not bear adequate directions for use and such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users.

(5) In the case of a restricted device, its advertising is false or misleading in any particular.

(6) In the case of a restricted device, advertisements and other descriptive printed matter (other than labeling) issued by the manufacturer, packer or distributor do not include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

In determining whether a device is misbranded because the labeling or advertising is misleading, the act permits the following to be taken into account among other things:

(1) representations made or suggested by statement, word, design, device, or any combination thereof; or

(2) the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to the consequences which may result from the use of the device to which the labeling or advertisingrelates under the conditions of use prescribed in the labeling or advertising or under such conditions of use as are customary or usual.

Regulations applicable to medical devices provide that the inclusion of any of the following representations in device labeling constitutes misbranding of the device:

False or misleading representation with respect o another device or a drug

Any representation that creates an impression of official approval because of registration or (e.g., inclusion of MMDA_FDA establishment registration number)

Any representation that creates an impression of official approval because of complying with the premarket notification regulations (e.g., inclusion of premarket notification reference number)

XIV. Prohibited Acts

The act prohibits the use in any labeling or advertising for the device of any representation or suggestion that approval of an application with respect to the device is in effect of the act (premarket approval) or that the device complies with the provisions of the act.