Guidance for Industry and FDA Staff

Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry and FDA Staff

Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s)

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 assist industry in preparing premarket notification submissions (510(k)) for menstrual tampons and pads that are subject to 510(k) requirements. This guidance covers the key recommendations for the content of 510(k) submissions for these devices. Depending on any unique design, technology, indications, and performance characteristics of a given product, FDA may recommend additional information not described in this guidance.

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 that we believe should 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 that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

2. Background

A manufacturer who intends to market a device of the generic types subject to this guidance should 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, and obtain a substantial equivalence determination from FDA prior to marketing the device.

This guidance document identifies the classification regulations and product codes for menstrual tampons and pads (Refer to Section **4. Scope**). In addition, other sections of this guidance document list the risks to health identified by FDA and describe measures that will generally address the risks associated with these menstrual tampons and pads and lead to a timely review and clearance. This document supplements other agency documents regarding the content requirements of a 510(k). You should also refer to CDRH's **Device Advice** http://www.fda.gov/cdrh/devadvice/ and 21 CFR 807.87.

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**[1]," a manufacturer may submit a Traditional 510(k) or has 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 FDA has issued a device-specific guidance document. Manufacturers considering modifications to their own cleared devices may 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); therefore, we recommend that you include a summary report. The report should describe how this guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 807.87, as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

[1] http://www.fda.gov/cdrh/ode/parad510.html

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. (Please refer to **Section 11. Labeling** for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

We recommend that the summary report contain the following.

Description of the device and its intended use

We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Please refer to section **5. Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[2]

Description of device design requirements

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

Identification of the risk analysis method

We recommend that you identify the risk analysis method(s) used to assess the risk profile for both the general and specific device's design. You should also include the results of this analysis. (Please refer to **Section 6. Risks to Health** for the risks to health identified by FDA that are generally associated with the use of this device.)

[2] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

Discussion of the device characteristics

We recommend that you include a discussion of 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 that you include a brief description of the test method(s) that you used or intend to use that address each performance aspect identified in **Sections 7-10** 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 should 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.[3] (See also 21 CFR 820.30, Subpart C - Design Controls under the Quality System Regulation.)

Reliance on standards

If any part of the device design or testing relies on a recognized standard, FDA recommends that you submit either:

- a statement that the device will meet specified acceptance criteria through testing prior to product marketing; or
- a declaration of conformity to the standard.[4]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing 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; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

If you do not clearly address the risks identified either by FDA (see **Table- Risks and Mitigation Measures**) or through your risk analysis, FDA may request additional information

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[3] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should 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 that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[4] See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), http://www.fda.gov/cdrh/ode/reqrecstand.html.

about aspects of the device's performance characteristics. We may request additional information to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), FDA may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), submission of a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance will suffice. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s. See also Appendix A.

The following is a specific discussion of how you should apply this guidance document to 510(k)s for menstrual tampons or pads.

4. Scope

Scented or scented-deodorized menstrual pads and unscented menstrual pads, made of materials with established safety profiles and that are not intralabial pads or reusable menstrual pads[5] are excluded from the scope of this guidance because they are exempt from 510(k).

Generally, FDA believes a material has an established safety profile if it has a history of safe use for similar intended uses and is physically and chemically well-characterized. The characterization of the material may be in the published literature, a previous submission, or a Device Master file.[6]

An intralabial pad is a menstrual pad intended worn externally and held in place by the labia. A reusable pad is one that may be washed, dried, and used again by the same woman.

The scope of this document is limited to the devices shown in the **Table 1** below.

Table 1. Classification and Product Codes for Menstrual Tampons and Pads subject to this guidance.

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[5] Scented or scented-deodorized menstrual pads that are not intralabial pads or reusable menstrual pads, made of materials with established safety profiles are classified in 21 CFR 884.5425 and assigned product code NRC. Unscented menstrual pads that are not intralabial pads or reusable menstrual pads, made of materials with established safety profiles are classified in 21 CFR 884.5435 and assigned product code HHD.

[6] Although traditionally referenced to support Premarket Approval Applications (PMAs), Master Files may also be referenced to support 510(k)s. For information about Device Master Files, see 21 CFR 814.3(d) and Device Advice at http://www.fda.gov/cdrh/dsma/pmaman/appdxc.html#P7_2.

Classification Regulation (21 CFR)	Class	Product Code	Description
884.5425 Scented or scented-deodorized menstrual pad[7]	II	HHL	Scented or scented-deodorized menstrual pads, including those intended as intralabial pads or reusable menstrual pads, made with materials or additives that do not have an established safety profile.[8]
	I	Not yet assigned	Scented or scented-deodorized menstrual pads intended as intralabial pads or reusable menstrual pads, including those made with materials or additives with established safety profiles.
884.5435 Unscented menstrual pad[7]	I	NUR	Unscented menstrual pad intended as an intralabial pad.
		NUQ	Unscented menstrual pad intended as a reusable pad.
		Not yet assigned	Unscented menstrual pad made with materials or additives that do not have an established safety profile
884.5460 Scented or scented-deodorized menstrual tampon	II	HIL	Scented or scented-deodorized menstrual tampon*
884.5470 Unscented menstrual tampon	II	HEB	Unscented menstrual tampon*

*If your device contains a drug or biologic, it is a combination product. See http://www.fda.gov/oc/combination/ for more information.

[7]We believe typographical errors ("intralabial" and "[intralabial]") were introduced when these classifications were amended (65 FR 2296, 2320 and 66 FR 38786, 38809). Both classifications should refer to intralabial pads as stated in the unamended classification (61 FR 67713, 67714). We plan to publish a correction in the Federal Register as soon as feasible.

[8] FDA believes a material has an established safety profile if it has a history of safe use for similar intended uses and is physically and chemically well-characterized.

5. Device Description

We recommend that you identify your device by regulation and product code. We also recommend that you provide a complete discussion of the design features, indications, and performance characteristics of your device. You should discuss the similarities and differences between your device and the predicate device in sufficient detail to permit FDA to fully assess your device and its similarities with the predicate device. We also recommend that you describe how any differences may affect the safety and effectiveness of your device. We recommend that you include the following in your discussion.

A. Design and Dimensions

Tampons

FDA recommends that you include engineering drawings of the tampon. We also recommend that you show the dimensions and materials for the:

- pledget
- overwrap (cover)
- removal string
- applicator (if any).

FDA also recommends that you provide a cross-sectional drawing to illustrate the design and dimensions of the tampon, both compressed and uncompressed.

Pads

FDA recommends that you include engineering drawings of the pad. We also recommend that you show the dimensions and materials for the:

- core
- overwrap (cover).

B. Absorbency Range

Tampons

We recommend that you provide specifications, including tolerances for the weight of the pledget (in grams), for each absorbency range of tampon in your submission.

Pads

Absorbency range as described in 21 CFR 801.430 does not apply to pads. See Design and Dimensions above instead.

C. Component Materials (including Additives)

For all component materials present in a tampon, applicator, or pad, we recommend that you provide:

- detailed chemical identity and quantity (in µg per tampon or pad) for all components, and any additives or finishing (e.g., anti-wicking) agents
- chemical identity of each component of any fragrance or deodorants
- references to any Device Master Files[6] for component materials, whenever possible.

We recommend that you summarize the information recommended above in a tabular format to show how your device compares with the predicate device (see sample format below).

Table 2. Device Comparison

Element	Your Device	Predicate (with 510(k) number, if available)
Design (e.g., shape of the tampon and applicator, if present)		
Dimensions • length • diameter (tampons only)		
Absorbency (grams) for each level (tampons only)		
Component Materials (chemical composition)		*
Additives and Finishing Agents		*
Other Features (if any)		

*(to the extent this information is available to you for devices made by other manufacturers)

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the menstrual tampons and pads within the scope of this document. The measures recommended to mitigate these risks are also shown in the table. You should also conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your device, especially if your device has any innovative or special features. The 510(k) should describe the risk analysis method and submit the results. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Table 3. Menstrual Tampons - Risks and Mitigation Measures

Identified risk	Recommended mitigation measures (see section indicated below)
adverse tissue reaction	7. Performance Characteristics 8. Preclinical Toxicology 10. Clinical Studies 11. Labeling
vaginal injury	10. Clinical Studies 11. Labeling
vaginal infection	11. Labeling
toxic shock syndrome (TSS)	9. Preclinical Microbiology 11. Labeling

Table 4. Menstrual Pads - Risks and Mitigation Measures

Identified risk	Recommended mitigation measures (see section indicated below)
adverse tissue reaction	7. Performance Characteristics 11. Labeling

7. Performance Characteristics

A. Tampons

Absorbency Range

Tampons must be labeled in accordance with 21 CFR 801.430. To determine the absorbency of menstrual tampons, you must use the "Syngyna testing" method as specified in 21 CFR 801.430(f)(2). We recommend you provide a summary of this testing in your submission for each absorbency level you plan to market.

Chemical Residues

FDA recommends that tampons be free of 2,3,7,8- tetrachlorodibenzo-p-dioxin (TCDD)/2,3,7,8-tetrachlorofuran dioxin (TCDF) and any pesticide and herbicide residues.[9]

You should describe any assurances that chemical residues are not present or, if residues are present, the level present and the method used to assess it. These assurances may include, but are not limited to, test methods, tolerances, or acceptance criteria. For any materials bleached during processing, we recommend that you identify the bleaching process used, e.g., Elemental Chlorine-Free (ECF) or Totally Chlorine-Free (TCF).

FDA also recommends that you demonstrate the performance characteristics for the following features of tampons:

- string strength
- fiber shedding
- tampon integrity.

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[9] FDA recommends that as a part of your design validation, you have in place validated test plans for monitoring dioxin and potential pesticide residues for cotton in tampon materials and final finished tampons. We recommend that you evaluate your device as described in your test plans and identify the test method and name and address of the testing laboratory in your design history file. You should also explain in your design history file whether testing was conducted on a prototype, on select or all batches, and on a fixed or "as needed" schedule. For more information on design validation and design history files, please see 21 CFR Part 820 Quality Systems.

B. Pads

For any pad materials that are bleached during processing, we recommend that you identify the bleaching process used, e.g., Elemental Chlorine-Free (ECF) or Totally Chlorine-Free (TCF).

In addition, FDA recommends that you demonstrate any device performance characteristics described in the labeling for such pads, such as washability or useable life. Generally, we anticipate the performance characteristics of these devices will be unique. The Obstetrics and Gynecology Devices Branch is available to discuss bench testing for your device before you prepare your 510(k).

8. Preclinical Toxicology

For tampons and pads, we recommend that you conduct biocompatibility testing as described in the FDA guidance, **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**, http://www.fda.gov/cdrh/g951.html (for repeat use devices--30 days or more-- in contact with skin/mucosal membrane surface). We recommend that you select biocompatibility tests appropriate for the duration and level of contact with your device. If *identical* materials are used in a predicate device with the same type and duration of user contact, you may identify the predicate device in lieu of providing biocompatibility testing in your submission.

9. Preclinical Microbiology

For tampon materials, we recommend that you demonstrate that the tampon, in its final manufactured form, does not:

- enhance the growth of Staphylococcus aureus
- increase the production of Toxic Shock Syndrome Toxin-1 (TSST-1)
- alter the growth of normal vaginal microflora.

There are no reference methods or recognized standards for testing S. aureus in tampons. We have included several methods in **Appendix B. References 2-7, and 9**. We recommend that you specify the test conditions, including cell culture medium and strains of S. aureus and other microorganisms used, and reference the methodology.

TSS is not a concern with the use of menstrual pads.

10. Clinical Studies

In accordance with the least burdensome provisions of the Act, FDA will rely upon well-designed bench and/or animal testing rather than requiring clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While, in general, clinical studies will not be needed for most menstrual tampons and pads, FDA may recommend that you collect clinical data for menstrual tampons (including applicators, if present) or pads with:

- designs or material formulations[10] dissimilar from designs or material formulations used in legally marketed devices of the same type
- new technology, i.e., technology different from that used in legally marketed devices of the same type
- indications for use dissimilar from legally marketed devices of the same type.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. The Obstetrics and Gynecology Devices Branch is available to discuss any questions you may have.

If clinical studies are necessary, we recommend that the studies evaluate:

- irritation
- allergy
- effects on vaginal microflora
- abrasions
- ulceration
- laceration
- residual fiber retention.

For any clinical study involving "ultra" absorbency tampons (i.e., 15-18 grams determined by Syngyna testing, as defined in 21 CFR 801.430), we recommend that you provide clinical information on fiber sloughing in vivo, in addition to the information above. If you have already begun marketing your "ultra" absorbency tampon in another country, we recommend that you include any published literature related to the use of your "ultra" absorbency tampon, in particular any literature related to that tampon and TSS.

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[10]If your device contains a drug or biologic, it is a combination product. See http://www.fda.gov/oc/combination/ for more information.

If subjects undergo a colposcopic examination during your clinical study to assess vaginal mucosa integrity, redness, and irritation or residual fiber retention related to tampon use, we recommend these examinations be conducted before and after the menses. We also recommend that these examinations be conducted by a healthcare professional. For guidance on conducting colposcopic examinations, please see **Manual for the Standardization of Colposcopy for the Evaluation of Vaginal Products, Update 2000.**[11]

FDA believes that the devices addressed in this guidance document are non-significant risk (NSR) devices. Therefore studies of these devices are subject to the abbreviated requirements of 21 CFR 812.2(b). In addition to the requirements 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).

As stated in 21 CFR 812.2(b), we consider studies on NSR devices to have approved applications for investigational device exemptions (IDEs), unless we have notified the sponsor otherwise. However, you may choose to submit a "pre-IDE" to help identify deficiencies that could preclude clearance of the resulting 510(k). You may submit a "pre-IDE" even though you are not going to submit an IDE to FDA. In this case, the "pre-IDE" should describe your study design, clinical protocol, and statistical plan, thus allowing the Obstetrics and Gynecology Devices Branch an opportunity to comment on these important elements before you initiate your study.[12]

After FDA determines that the device is substantially equivalent, clinical studies conducted in accordance with the indications reviewed in the 510(k), including clinical design validation studies conducted in accordance with the quality systems regulation, are exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance with 21 CFR 56 and 21 CFR 50.

11. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions offer assistance in preparing labeling that satisfies the requirements of 21 CFR Part 801.[13]

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[11] Reference WHO/RHR/00.11 - CONRAD/2000.1, http://www.who.int/reproductive-health/publications/Abstracts/colposcopy_evaluation.html

[12] See also **Pre-IDE Program: Issues and Answers, March 25, 1999 (D99-1),** http://www.fda.gov/cdrh/ode/d99-1.html.

[13] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. For tampons, this includes complying with 21 CFR 801.430, "User labeling for menstrual tampons." Labeling recommendations in this guidance are consistent with the requirements of part 801.

A. Tampons and Pads

User instructions for menstrual tampons and pads should familiarize users with the features of the device and how to use it in a safe and effective manner and include a description of the product and the materials it contains.

B. Tampons only

For menstrual tampons, in addition to the labeling information required by 21 CFR 801.430(d) and 21 CFR 801.430(e), user instructions should include information on:

- selection of tampon size and absorbency
- tampon insertion
- how tampon should be worn and wear-time
- tampon removal and disposal.

To avoid risk of TSS, we recommend that you include instructions that:

- limit wear-time per tampon to no more than 8 hours
- advise against the use of tampons "overnight."

Rates of reported TSS cases associated with tampons have decreased significantly over the past 20 years (Reference 8). We believe more informative tampon labeling and educational efforts by the FDA and tampon manufacturers have played key roles in this decrease. Therefore, FDA recommends continued caution when developing tampon labeling.[14]

For scented or scented-deodorized tampons, we also recommend that you include a warning statement about allergic reactions and irritations, for example:

> If an allergic reaction or irritation occurs from using tampons, you should discontinue use and consult a medical professional.

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[14] We recommend that you draft labeling that helps ensure consumer (adult and teen) comprehension of safety information about tampons and TSS, as well as helps avoid unintended effects on consumer behavior that might increase the risk of TSS. We recommend that you document the results of any evaluation such as focus testing in your design history file.

Appendix A. Modifying a Legally Marketed Tampon

If you change or modify your legally marketed device in a way that significantly affects its safety or effectiveness, you must submit a new 510(k). 21 CFR 807.81(a)(3). Generally, FDA believes the modifications listed below significantly affect the safety or effectiveness of a tampon:

- dissimilar indications for use
- new device materials or additives
- modifications resulting in a design that is dissimilar from the legally marketed design
- modification of a legally marketed tampon to achieve a 15-18 gram absorbency (as shown by Syngyna test).

FDA believes that the modifications listed below generally do not affect safety and effectiveness:

- changing ratios of absorbent materials in tampon pledget. For example, changing from 50/50 cotton and rayon to 80% cotton and 20% rayon.[15]
- adding an absorbency range, other than "ultra" (15-18 gram) to a manufacturer's legally marketed design, consistent with the absorbency ranges specified in 21 CFR 801.430(e)(1).

When a modification does not affect the intended use or alter the fundamental scientific technology of the device, but requires a new 510(k) in accordance with 21 CFR 807.81(a)(3), FDA recommends you submit a Special 510(k).[16]

In any 510(k) for a change or modification to a legally marketed tampon, we recommend that you describe the modification and its effects and provide supporting information (such as a risk analysis, performance characteristics, or preclinical or clinical information) demonstrating that the modification does not adversely affect safety or effectiveness. For additional guidance about modifying legally marketed devices, please see "**Deciding When to Submit a 510(k) for a Change to an Existing Device**" http://www.fda.gov/cdrh/ode/510kmod.html.

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[15] If the absorbency range changes as a result, we recommend that you document these changes in your design history file.

[16] See **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, http://www.fda.gov/cdrh/ode/parad510.html.

Appendix B. References

1. Manual for the Standardization of Colposcopy for the Evaluation of Vaginal Products, Update 2000, WHO.

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