The
New 510(k)
Paradigm

Alternate Approaches
to Demonstrating Substantial Equivalence
in Premarket Notifications

Final Guidance

This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Prepared by the
Center for Devices and Radiological Health

March 20, 1998

Comments and suggestions may be submitted at any time for Agency consideration to Heather Rosecrans, Office of Device Evaluation, 10903 New Hampshire Avenue, Silver Spring, MD 20993. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, contact Heather Rosecrans at 301-796-6571 or e-mail heather.rosecrans@fda.hhs.gov.

For additional copies: World Wide Web/CDRH home page: http://www.fda.gov/cdrh. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy.

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Preface

As part of the Center for Devices and Radiological Health's (CDRH) organizational transformation initiative, the 510(k) Process Reengineering Team examined the existing process through which regulated industry demonstrates substantial equivalence of medical devices in premarket notifications (510(k)s). On June 13, 1997, the Food and Drug Administration (FDA) released a draft proposal entitled, "A New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" for comment on the Internet. The proposal was the subject of two videoconferences which were co-sponsored by FDA and the Food and Drug Law Institute (FDLI) and was also discussed at several trade and industry association meetings. On September 19, 1997, the Agency published a Notice of Availability of the proposal in the Federal Register (62 FR 49247) to formally solicit comments from interested parties.

During this same period of time, the United States Congress was in the process of drafting the FDA Modernization Act of 1997 (the FDAMA)(Pub. L. 105-115), which amended the device provisions of the Federal Food, Drug, and Cosmetic Act (the Act). During its deliberations over the new law, several of the concepts in the New 510(k) Paradigm were discussed by members of Congress. On November 21, 1997, the President of the United States signed into law the FDAMA, which incorporated many of the changes proposed in the New Paradigm as well as many others that were envisioned in the Center's reengineering efforts. As a direct result of the enactment of this new law and the comments that were received during the period of public review, the 510(k) Process Reengineering Team developed this final guidance document.

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Introduction

This document provides guidance to the regulated industry and reviewers on two alternative approaches that may be used, under appropriate circumstances, to demonstrate substantial equivalence. It establishes procedures regarding the use of consensus standards in the premarket review process (section 514 of the Act, as amended by section 204 of the FDAMA) and reflects other changes to the 510(k) Program that have resulted from enactment of the new law, such as increased reliance on postmarket controls to expedite premarket review (section 513 of the Act, as amended by section 205 of the FDAMA). In addition, it incorporates concepts that have arisen out of the Center's organizational transformation initiative, including a new emphasis on the use of guidance documents and special controls. The alternative approaches described in this guidance document should streamline the 510(k) preparation and review processes, thus conserving industry and Agency resources while still protecting the public health.

Background

Under section 510(k) of the Act, a person who intends to introduce a device into commercial distribution is required to submit a premarket notification, or 510(k), to FDA at least 90 days before commercial distribution is to begin. Section 513(i) of the Act states that FDA may issue an order of substantial equivalence only upon making a determination that the device to be introduced into commercial distribution is as safe and effective as a legally marketed device. Under 21 CFR 807.87, FDA established the content requirements for premarket notifications to be submitted by device manufacturers in support of the substantial equivalence decision. FDA has, however, discretion in the type of information it deems necessary to meet those content requirements. For example, to allocate review resources more effectively to the highest risk devices, FDA developed a tiering system based on the complexity and the level of risk posed by medical devices. Under this system, the substantial equivalence determination for low risk devices is based primarily on descriptive information and a labeling review, while the decision for higher risk devices relies on performance data.

In a further effort to manage FDA's workload and allocate resources most appropriately, the Agency exempted Class I devices for which it determined that premarket notification requirements were not necessary to provide reasonable assurance of safety and effectiveness.

Between the passage of the Medical Device Amendments of 1976 and the FDAMA, FDA exempted 574 generic types of Class I devices from the requirement of premarket notification. As a result of the FDAMA, all Class I devices are exempt from the requirement of premarket notification, unless the device is intended for a use that is of substantial importance in preventing impairment to human health or presents a potential unreasonable risk of illness or injury ("reserved" criteria). Therefore, only those Class I devices that meet the reserved criteria remain subject to the premarket notification requirement. (See 63 FR 5387, February 2, 1998, for a listing of Class I "reserved" devices.)

The FDAMA also gave FDA the authority to directly exempt certain Class II devices rather than first down-classifying them to Class I before they become eligible for exemption. On January 21, 1998, FDA published a listing of Class II devices that no longer require premarket notification. (See 63 FR 3142.) In the future, additional Class II devices may become exempt from the premarket notification requirement as FDA considers additional devices for exemption.

The last phase of the Agency's effort to evaluate which devices should be subject to 510(k) review involves the preamendments Class III devices. Preamendments Class III devices for which general controls or special controls are sufficient to ensure safety and effectiveness will eventually be down-classified to either Class I (510(k) exempt or reserved) or to Class II, respectively. Those preamendments Class III devices that are not appropriate for reclassification will remain in that class and be subject to either premarket approval (PMA) or product development protocol (PDP) requirements. It is anticipated that, as a result of this reclassification effort, the premarket notification process will be primarily reserved for Class II devices and a few "reserved" Class I devices. Until a preamendments Class III device type becomes subject to a regulation requiring premarket approval, however, the device type will remain subject to the premarket notification requirement.

The New 510(k) Paradigm

To streamline the evaluation of premarket notifications for the reserved Class I devices, Class II devices subject to premarket notification, and preamendments Class III devices for which FDA has not yet called for PMAs, the Agency has developed "The New 510(k) Paradigm." Attachment 1 outlines the New Paradigm, which presents device manufacturers with two new optional approaches for obtaining marketing clearance for devices subject to 510(k) requirements. While the New Paradigm maintains the traditional method of demonstrating substantial equivalence under section 510(k) of the Act, it also presents the "Special 510(k): Device Modification" option, which utilizes certain aspects of the Quality System Regulation, and the "Abbreviated 510(k)" option, which relies on the use of guidance documents, special controls, and recognized standards to facilitate 510(k) review. Use of either alternative, however, does not affect FDA's ability to obtain any information authorized by the statute or regulations.

A. Special 510(k): Device Modification

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629) amended section 520(f) of the Act, providing FDA with the authority to issue regulations requiring pre-production design controls. Specifically, section 520(f)(1)(A) states that FDA may prescribe regulations to require "... that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act." This change in the law was based on findings that a significant proportion of device recalls were attributed to faulty design. Under the authority provided by the SMDA, FDA revised its current good manufacturing practice requirements to include pre-production design controls that device manufacturers must follow when initially designing devices or when making subsequent modifications to those designs. (See 21 CFR 820.30 Subpart C - Design Controls of the Quality System Regulation.)

Effective June 1, 1997, manufacturers of Class II, Class III, and certain Class I devices are required to follow design control procedures when originally developing devices and for subsequent modifications. Product modifications that could significantly affect safety and effectiveness are subject to 510(k) submission requirements under 21 CFR 807 as well as design control requirements under 21 CFR 820.30. In accordance with the Quality System Regulation, manufacturers must have a systematic set of requirements and activities for the management of design and development, including documentation of design inputs, risk analysis, design output, test procedures, verification and validation procedures, and documentation of formal design reviews. In this process, the manufacturer must ensure that design input requirements are appropriate so the device will meet its intended use and the needs of the user population. The manufacturer must also establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Thus, manufacturers may need to refine their device design requirements as verification and validation results are obtained. The design specifications that result from this process are the design outputs, which form the basis for the device master record (DMR). (See 21 CFR 820.3(i).) The DMR is subject to inspection by FDA personnel.

Since design control requirements are now in effect and require the manufacturer to conduct verification and validation studies of a type that have traditionally been included in 510(k) submissions, the Agency believes that it may be appropriate to forgo a detailed review of the

underlying data normally required in 510(k)s. For this reason, FDA is allowing an alternative to the traditional method of demonstrating substantial equivalence for certain device modifications. For these well-defined modifications, the Agency believes that the rigorous design control procedure requirements produce highly reliable results that can form, in addition to the other 510(k) content requirements specified in Attachment 2, a basis for the substantial equivalence determination. Under the Quality Systems Regulation, data that is generated as a result of the design control procedures must be maintained by the manufacturer and be available for FDA inspection.

Under the New 510(k) Paradigm, a manufacturer should refer to 21 CFR 807.81(a)(3) and the FDA guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" to decide if a device modification may be implemented without submission of a new 510(k). If a new 510(k) is needed for the modification and if the modification does not affect the intended use of the device or alter the fundamental scientific technology of the device, then summary information that results from the design control process can serve as the basis for clearing the application.[1]

Under this option of the Paradigm, a manufacturer who is intending to modify his/her own legally marketed device[2] will conduct the risk analysis and the necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design input requirements. Once the manufacturer has ensured the satisfactory completion of this process, a "Special 510(k): Device Modification" may be submitted. While the basic content requirements of the 510(k) (21 CFR 807.87) will remain the same, this type of submission should also reference the cleared 510(k) number[3] and contain a "Declaration of Conformity" with design control requirements. Refer to Attachment 2 for the contents of a "Special 510(k): Device Modification" with a "Declaration of Conformity" to design controls.

Under the Quality System Regulation, manufacturers are responsible for performing internal audits to assess their conformance with design controls. A manufacturer could, however, use a

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[1] The terms "intended use" and "fundamental scientific technology" are used in the same manner as when used to define the limitations of exemptions from section 510(k) of the Act as found in each of the product classification regulations, 21 CFR 862-892, e.g., 21 CFR §§862.9, 864.9, and 866.9.

[2] Although not subject to the design control procedure requirements of the Quality System Regulation, manufacturers of reserved Class I devices may elect to comply with this provision of the regulation and submit Special 510(k)s.

[3] Manufacturers of preamendments devices may submit Special 510(k)s. See footnote 6 of Attachment 2 for information that should be included in a Special 510(k) under this circumstance.

third party[4] to provide a supporting assessment of the conformance. In this case, the third party will perform a conformance assessment for the device manufacturer and provide the manufacturer with a statement to this effect. The marketing application should then include a declaration of conformity signed by the manufacturer, while the statement from the third party should be maintained in the DMR. As always, responsibility for conformance with design control requirements rests with the manufacturer.

In order to provide an incentive for manufacturers to choose this option for obtaining Agency clearance for device modifications, the Office of Device Evaluation (ODE) intends to process Special 510(k)s within 30 days of receipt by the Document Mail Center (DMC). The Special 510(k) option will allow the Agency to review modifications that do not affect the device's intended use or alter the device's fundamental scientific technology within this abbreviated time frame. The Agency does not believe that modifications that affect the intended use or alter the fundamental scientific technology of the device are appropriate for review under this type of application, but rather should continue to be subject to the traditional 510(k) procedures (i.e., "Traditional 510(k)") or may be subject to an Abbreviated 510(k) as described below.

FDA believes that to ensure the success of the Special 510(k) option of the Paradigm, there must be a common understanding of the types of device modifications that may gain marketing clearance by this path. In this vein, it is critical that industry and Agency staff can easily determine whether a modification is appropriate for submission as a Special 510(k). To optimize the chance that a Special 510(k) will be accepted and promptly cleared, 510(k) submitters should evaluate each modification against the considerations described below to insure that the particular change does not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

I. Intended Use

As discussed earlier, modifications to the indications for use of the device or any labeling change that affects the intended use of the device should not be submitted as a Special 510(k). Therefore, FDA recommends that submitters of Special 510(k)s highlight, or otherwise prominently identify, all changes in the proposed labeling that may result from modifications to their legally marketed device. In addition, it should be clearly stated in the Special 510(k) that the intended use of the modified device, as described in its labeling, has not changed as a result of the modification(s).

[4] This use of a third party should not be confused with the Agency's Third Party Review Program where recognized third parties review entire 510(k) submissions.

II. Fundamental Scientific Technology

Special 510(k)s should also not be submitted for modifications that have the potential to alter the fundamental scientific technology of the device. These types of changes generally include modifications to the device's operating principle(s) or mechanism of action, such as automation of a manual device or incorporation of a sensing or feedback circuit. Specific examples that illustrate these types of changes that alter the fundamental scientific technology and thus should not be submitted as Special 510(k)s include:

1. A change in a surgical instrument that uses a sharpened metal blade to one that cuts with at a laser;

2. A change in an *in vitro* diagnostic (IVD) device that uses immunoassay technology to one that uses nucleic acid hybridization or amplification technology;

3. Incorporation of a sensing mechanism in a device to allow the device to function "on demand" rather than continuously.

In addition, the Agency is concerned with changes in materials in certain devices. While FDA acknowledges that many such changes can be processed as Special 510(k)s, there are certain types of changes in materials that may raise safety or effectiveness issues that continue to warrant a more intensive evaluation by the Agency. This includes a change in material(s) in an implant, or other device that contacts body tissues or fluids, to a material type that has not been used in other legally marketed devices within the same classification regulation for the same intended use (i.e., "legally marketed predicate device"). For example, a change in a material in a finger joint prosthesis from a known metal alloy to a ceramic that has not been used in a legally marketed predicate, should not be submitted as a Special 510(k). Similarly, a change in a device's active ingredient or agent to one that has not been used in other legally marketed predicate devices should not be submitted for review as a Special 510(k). For example, if a manufacturer of a contact lens disinfecting solution wanted to change from hydrogen peroxide to an antiseptic that had not been previously used in a legally marketed predicate, such a change would not be appropriate for review as a Special 510(k). Both of the above types of modifications involve major changes in the principle component of the device and thus would be considered a change to the fundamental scientific technology of the device and should be submitted for review as either Abbreviated or Traditional 510(k)s.

A change, however, in formulation in a material or a change to a type of material that has been used in other legally marketed devices within the same classification regulation for the same intended use could be reviewed as a Special 510(k). This should be true for both non-contacting devices as well as implants and devices that contact body tissues or fluids. Thus, a manufacturer of a hip implant could change from one alloy to one that has been

used in another legally marketed predicate through the submission of a Special 510(k). Similarly, a contact lens manufacturer could submit a Special 510(k) for a change in their polymer to another material that has been used in a legally marketed predicate. Finally, changes in an inactive or secondary ingredient/agent should be appropriate for review as Special 510(k)s as this should not be considered a major change to the fundamental scientific technology of the device. For example, a manufacturer of a urologic catheter could submit a Special 510(k) to add an antimicrobial coating to the device if the coating has been used on another legally marketed predicate of the same material.

Device modifications that should be appropriate for review as Special 510(k)s also include those changes identified below:

a. Energy type
b. Environmental specifications
c. Performance specifications
d. Ergonomics of the patient-user interface
e. Dimensional specifications
f. Software or firmware
g. Packaging or expiration dating
h. Sterilization

It should be noted that in cases where FDA has issued guidance, established special controls, or recognized standards that address issues such as device testing or performance, manufacturers should consider this in their implementation of design control requirements. For example, if a manufacturer is modifying a contact lens, then the manufacturer's design control inputs should include the special controls that FDA has established for this device. Further, if a manufacturer modifies an *in vitro* diagnostic, the manufacturer's design inputs should include any recognized clinical standards such as those developed by the National Committee of Clinical Laboratory Standards (NCCLS) or a reasonable alternative. Thus, submitters of Special 510(k)s need to be aware of any relevant guidance documents, special controls, or recognized standards that apply to their device and that should be addressed by their design control processes.

III. Clinical Considerations

FDA recognizes that clinical evaluation may be involved in the validation of the design of a modified device. Manufacturers are reminded that all clinical investigations must conform to the applicable regulations, including 21 CFR Parts 812, 50 and 56. Therefore, collection of clinical data to support a Special 510(k) may require submission of an investigational device exemptions (IDE) application to FDA. The fact that a significant risk device investigation was conducted to support any of the activities listed above, however, does not necessarily preclude the submission of a Special 510(k).

Manufacturers who intend to conduct clinical investigations of a modified device as part of design validation are encouraged to contact the appropriate ODE review division before preparing a Special 510(k). When a clinical investigation is necessary to answer safety and effectiveness questions relating to a particular modification, the Agency believes that the modification is likely to have gone beyond that which is suitable for review as a Special 510(k). In contrast, where design validation involves clinical evaluation intended to ensure that the modified device meets user requirements as opposed to patient safety and effectiveness or to demonstrate continued conformance with a special control or recognized standard, FDA believes that the Special 510(k) may be the appropriate submission.

B. Abbreviated 510(k)

Over the past few years, FDA has been placing greater emphasis on the development of guidance documents to communicate regulatory and scientific expectations to industry. In the 510(k) area, numerous guidance documents exist, while others are under development for Class I, Class II and preamendments Class III devices. With the advent of Good Guidance Practices, device-specific guidance documents are developed with public participation. The main focus of these guidance documents is the identification of the information recognized as appropriate for marketing authorization. FDA believes that use of these device-specific guidances may provide an effective means of streamlining the review of 510(k)s through a reliance on a "summary report" outlining adherence to relevant guidance documents. A 510(k) submission that conforms with an FDA guidance document should be easier to prepare and review, thus resulting in a more expeditious evaluation and clearance of the 510(k).

The SMDA introduced the concept of special controls as a means by which the safety and effectiveness of Class II devices can be assured. Special controls are defined in section 513(a)(1)(B) of the Act as those controls, such as performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations and other appropriate actions that provide reasonable assurance of the device's safety and effectiveness. As in the case of guidance documents, summary information that describes how a special control(s) has been used to address a specific risk or issue should reduce the time and effort to prepare and review 510(k)s.

In addition to device-specific guidance documents (hereinafter referred to as guidance documents) and special controls, CDRH is committed to recognizing individual consensus standards. In fact, the FDAMA amended section 514 of the Act to specifically authorize the Agency to recognize all or part of national and international standards through publication of a notice in the Federal

Register. Recognized standards could be cited in guidance documents or individual policy statements, or established as special controls that address specific risks associated with a type of device. IEC 60601-1 is an example of such a consensus standard. It has broad applicability to many electromedical devices. FDA's recognition of this standard, combined with modified review procedures, should streamline the review of many 510(k)s for devices covered by the standard. Finally, by using accompanying particular standards to adapt a general standard to a specific device, the 510(k) review process may be further expedited.

Therefore, device manufacturers may choose to submit an Abbreviated 510(k) when: (1) a guidance documents exists, (2) a special control has been established, or (3) FDA has recognized a relevant consensus standard.[5] An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87. In addition, manufacturers submitting an Abbreviated 510(k) that relies on a guidance document and/or special control(s) should include a summary report that describes how the guidance document and/or special control(s) were used during device development and testing. (See Attachment 3.) The summary report should include information regarding the manufacturer's efforts to conform with the guidance document and/or special control(s) and should outline any deviations. Persons submitting an Abbreviated 510(k) that relies on a recognized standard should provide the information described in Attachment 3 (except for the summary report) and a declaration of conformity to the recognized standard. (See Attachment 4.) Such persons should also refer to the Agency's guidance entitled, "Guidance on the Recognition and Use of Consensus Standards."

In an Abbreviated 510(k), a manufacturer will also have the option of using a third party to assess conformance with the recognized standard. Under this scenario, the third party will perform a conformance assessment to the standard for the device manufacturer and should provide the manufacturer with a statement to this effect. Like a Special 510(k), the marketing application should include a declaration of conformity signed by the manufacturer, while the statement from the third party should be maintained in the DMR pursuant to the Quality System Regulation. Responsibility for conformance with the recognized standard, however, rests with the manufacturer, not the third party.

The incentive for manufacturers to elect to provide summary reports on the use of guidance documents and/or special controls or declarations of conformity to recognized standards will be an expedited review of their submissions. While abbreviated submissions will compete with traditional 510(k) submissions, it is anticipated that their review will be more efficient than that of traditional submissions, which tend to be data intensive. In addition, by allowing ODE reviewers to rely on a manufacturer's summary report on the use of a guidance document and/or special controls and declarations of conformity with recognized standards, review resources can be directed at more complicated issues and thus should expedite the process.

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[5] For a current list of FDA recognized standards, please refer to CDRH's home page at http://www.fda.gov/cdrh or CDRH's Facts on Demand at 1-800-899-0381.

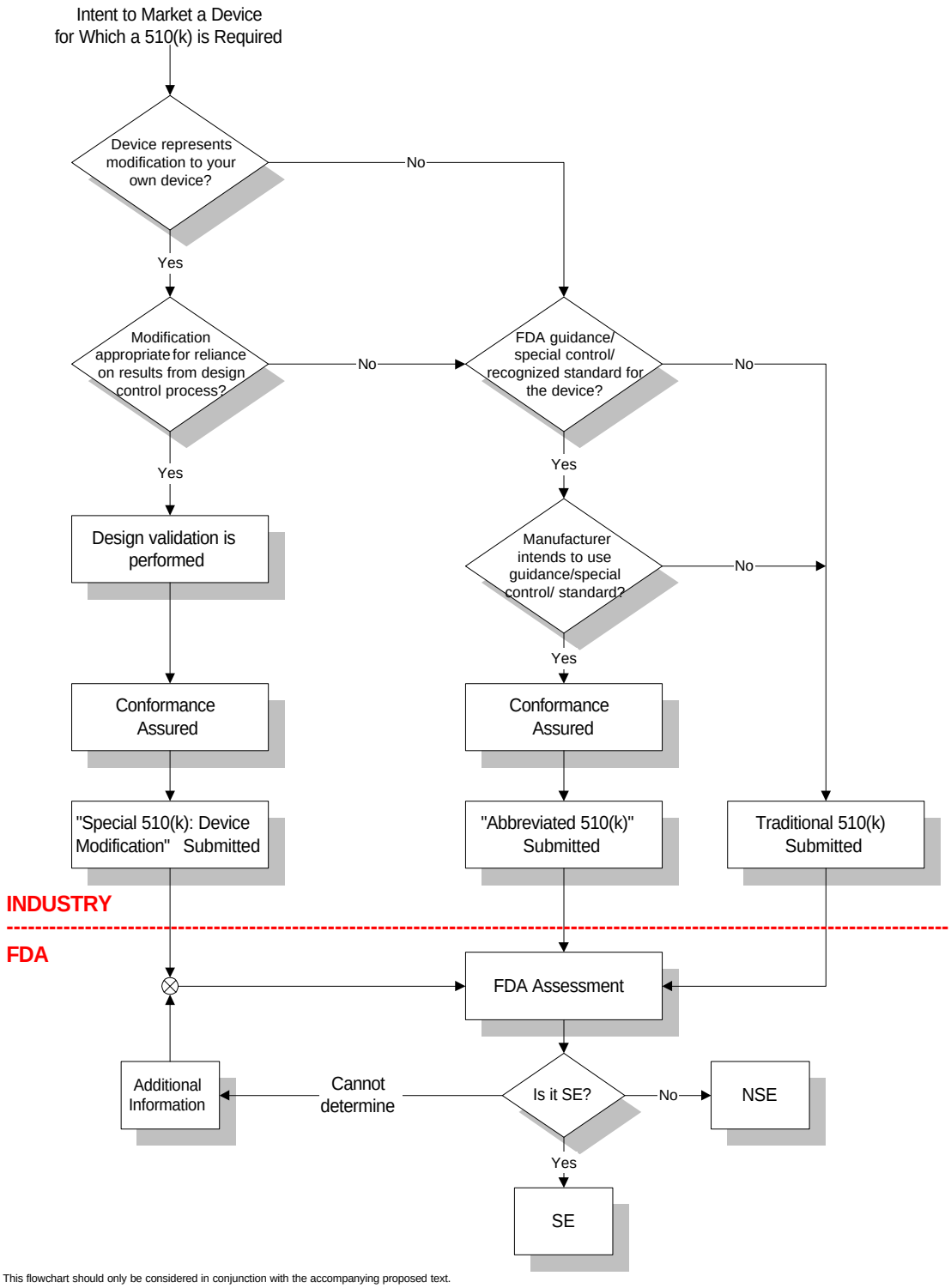
Conclusion

FDA believes that the New 510(k) Paradigm will provide considerable flexibility for the medical device industry in demonstrating substantial equivalence in 510(k) submissions. The principles presented in this guidance document will be implemented through changes in the administrative processes and do not require changes to either the premarket notification regulation (21 CFR 807 Subpart E Premarket Notification Procedures) or to the Act. As experience is gained by the industry in preparing Special and Abbreviated 510(k)s and by FDA in evaluating these new types of 510(k) submissions, this guidance document may be updated and revised. CDRH will create and update a "New 510(k) Paradigm" website on the CDRH home page with information regarding this guidance as it becomes available. Device manufacturers should access this website for copies of Special/Abbreviated 510(k) coversheets, checklists, and additional information regarding implementation of the New Paradigm.

Effective Date: This guidance document is effective March 20, 1998.

Attachment 1

The New 510(k) Paradigm



This flowchart should only be considered in conjunction with the accompanying proposed text.

Attachment 2
"Special 510(k): Device Modification"
Content

A Special 510(k): Device Modification should include:

- A coversheet clearly identifying the application as a "Special 510(k): Device Modification";

- The name of the legally marketed (unmodified) device and the 510(k) number under which it was cleared[6,7] ;

- Items required under §807.87, including a description of the modified device and a comparison to the cleared device, the intended use of the device, and the proposed labeling for the device;

- A concise summary of the design control activities. FDA may consider the information generated from these activities to be "appropriate supporting data" within the meaning of §807.87(g). This summary should include the following:

    - An identification of the Risk Analysis method(s) used to assess the impact of the modification on the device and its components as well as the results of the analysis;

    - Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and the acceptance criteria applied; and

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[6] When the legally marketed (unmodified) device is a preamendments device, the submitter should clearly state that the device is a preamendments device, is legally marketed, and has not been the subject of premarket notification clearance. (Refer to "Documentation Required for Preamendments Status" for the procedures for demonstrating preamendments status. Submitters should maintain this information in their files.)

[7] In cases where the referenced 510(k) was submitted under a different name than that of the submitter of the Special 510(k), the Agency recommends that a statement to this effect be included in the Special 510(k) and that the submitter maintain adequate information demonstrating his legal right to distribute the device.

- A declaration of conformity with design controls. The declaration of conformity should include:

    1) A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and

    2) A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.[8]

    ** The above two statements should be signed by the designated individual(s) responsible for those particular activities.

- Indications for Use enclosure.

[8] If a recent Quality System inspection has resulted in the issuance of a violative inspection report, the manufacturer should be prepared to describe those corrective actions taken, if needed, that form the basis for the declaration of conformity.

Attachment 3
"Abbreviated 510(k)"
Content

An Abbreviated 510(k) should include:

- A coversheet clearly identifying the application as an "Abbreviated 510(k)";

- Items required under §807.87, including a description of the device, the intended use of the device, and the proposed labeling for the device;

- For a submission that relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) were used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternative approach to address a particular risk, sufficient detail should be provided to justify that approach.);

- For a submission that relies on a recognized standard, a declaration of conformity to the standard. (The declaration should be submitted in accordance with Attachment 4.);

- Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards; and

- Indications for Use enclosure.

Attachment 4
Declaration of Conformity to a Recognized Standard

In preparing a declaration of conformity to recognized standards, manufacturers should refer to the guidance document entitled, "Guidance on the Recognition and Use of Consensus Standards." In accordance with this guidance, declarations of conformity to recognized standards should include the following:

- An identification of the applicable recognized consensus standards that were met;

- A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below;

- An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed;

- An identification, for each consensus standard, of any requirements that were not applicable to the device;

- A specification of any deviations from each applicable standard that were applied (e.g., deviations from international standards which are necessary to meet U.S. infrastructure conventions such as the National Electrical Code (ANSI/NFPA 70));

- A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference; and

- The name and address of any test laboratory or certification body involved in determining the conformance of the device with the applicable consensus standards and a reference to any accreditations of those organizations.