

Guidance for Industry and for FDA Staff

Use of Standards in Substantial Equivalence Determinations

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to the 510(k) Staff, HFZ-404, Office of Device Evaluation, 9200 Corporate Boulevard, Rockville, MD 20850. 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 240-276-4021.

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Use of Standards in Substantial Equivalence Determinations¹

Purpose

This guidance document is intended to clarify for industry and for reviewers in the Office of Device Evaluation (ODE) the ways in which standards may be used in demonstrating substantial equivalence in premarket notification (510(k)) submissions. Previous guidance has discussed the use of declarations of conformity to standards recognized by FDA under the newly created Section 514 (c) (Recognition of a Standard) of the Federal Food, Drug, and Cosmetic Act (the Act). This document expands upon that guidance by discussing the use of FDA-recognized standards in 510(k)s that do not contain a declaration of conformity, and the use of non-recognized standards.

Background

Standards historically have had a significant role in addressing information needs for substantial equivalence determinations. Information in a 510(k) submission about a device's conformity with a standard has helped to characterize the device and has substituted for detailed descriptive information or performance data.² For example:

- 510(k)s for external infusion pumps typically contain information on the chemical formulation and biocompatibility of device materials that contact the fluid path. Manufacturers have identified metal components of these devices using ASTM material specification standards (e.g., “ASTM 316 stainless steel”). Because the characteristics of materials meeting these standards are well established, ODE generally has accepted this means of identification in place of detailed descriptive specifications, and has not required biocompatibility test data for components identified as being made of these materials.
- 510(k)s for ophthalmic devices have traditionally characterized the electrical safety of a device in terms of conformance with standards such as UL-544 or IEC 60601-1. ODE has accepted statements that devices will conform to one of these standards in place of measurement data.
- 510(k)s for certain radiology devices (e.g., x-ray systems) have addressed various safety issues by including a statement that the device will meet applicable requirements of

¹ 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.

² Information on conformity with a standard has appeared in various parts of a 510(k), such as in the cover letter, device description, device labeling, or in a stand-alone statement.

FDA's regulatory performance standard for ionizing radiation-emitting products. In addition, 510(k)s for these devices have addressed mechanical and electrical safety issues by providing a statement that the devices will conform to UL-187 or IEC 60601-1.

- 510(k)s for noninvasive blood pressure measurement systems typically include performance testing data because descriptive characteristics alone may not be precise enough to ensure equivalence. Rather than always requiring data from comparative testing of the new device and a legally marketed device, ODE has accepted information on conformity with the ANSI/AAMI SP10 standard, which includes provisions for performance testing.

In instances such as these, the standards addressed safety and effectiveness issues that could have a bearing on substantial equivalence determinations. Conformity with a standard meant a new device was similar to previously marketed devices in the areas covered by the standard. Thus, information on the device's conformity with a standard could take the place of detailed comparisons between the new device and previously marketed devices. This approach has been used successfully to streamline many 510(k) submissions and to reduce the resources required for ODE's reviews, while still providing a sound basis for substantial equivalence determinations. In cases where standards better reflected the current state-of-the-art than pre-1976 predicate devices, this approach has provided a greater assurance of safety and effectiveness than comparisons to predicate devices.

Because 510(k)s notify the agency of a manufacturer's *proposal* to market a device, and must be submitted at least 90 days before the device is to be introduced, 510(k)s normally are submitted before a manufacturer is prepared to produce the device or to conduct finished product testing. Consequently, most 510(k) substantial equivalence determinations have been based primarily on descriptive information (i.e., device specifications, draft labeling, etc.) without the submission of test data to confirm that a device, in fact, conforms to its specifications.³ Similarly, in cases where conformity with a standard adequately addresses relevant premarket requirements, ODE frequently has accepted a statement that a device conforms (or will conform before marketing) to the standard, without requiring the submission of data demonstrating conformity (which, in most cases, would require testing of final production units). ODE has viewed such statements in the same manner as other device specifications in the 510(k); that is, they must be fulfilled before the device is introduced to the market. There is a strong legal basis for ODE's reliance on these statements.⁴

³ In contrast, a premarket approval application (PMA) typically must contain "...full reports of all information...to show whether or not [a] device is safe and effective" (Section 515(c)(1)(A)).

⁴ A device is in violation of the Act, and may be subject to FDA enforcement action, if a manufacturer markets the device without fulfilling a statement in a 510(k) that ODE relied upon in making a substantial equivalent determination. First, it is a prohibited act for a manufacturer to submit a 510(k) that is false or misleading in any material respect. In fact, under 21 CFR 807.87(k), manufacturers must include a statement in a 510(k) that the information submitted is truthful and accurate. Second, only devices that do not differ significantly from the specifications described in a 510(k) (including conformity with a standard) are the subject of a substantial equivalence determination for the 510(k) and can be legally marketed based on that clearance. Devices that do not have a required 510(k) clearance are adulterated and misbranded, and marketing an adulterated or misbranded device is a prohibited act. Third, manufacturers are required under the agency's Quality Systems

Nonetheless, for some uses of standards, ODE has determined that it could not rely solely on a statement about conformity. This has stemmed from a variety of factors, including: unfamiliarity with a standard; concern that a standard lacked specificity in areas such as test methodology or performance criteria; or existence of device features that were not addressed by a standard. In these instances, ODE typically has requested more information on the standard, information specifying how a device met the standard, or information on issues that the standard did not adequately address. For example, in 510(k)s for noninvasive blood pressure measurement systems that cite a standard other than the ANSI/AAMI SP10 standard, mentioned above, ODE traditionally has requested a comparison of the standard to the ANSI/AAMI SP10 standard.

As a result of these variations in the way standards have been used, as well as the absence of an overall list of “acceptable” standards, manufacturers sometimes have been uncertain whether ODE was willing to rely upon a standard, and how much supporting documentation was necessary in a 510(k). Delays could occur when a 510(k) cited a standard that ODE’s reviewers believed was inadequate or that was unfamiliar to them. To reduce this uncertainty and to encourage use of standards, the Food and Drug Administration Modernization Act of 1997 (FDAMA) created Section 514(c) of the Act.

Section 514(c) gives manufacturers explicit authority to use FDA-recognized standards to meet requirements of the Act. Section 514(c) directs FDA to recognize national and international standards by publication in the *Federal Register*, and allows manufacturers--if they elect to conform to any of these standards--to submit a declaration of conformity to FDA. It mandates that FDA will accept a manufacturer’s declaration of conformity to an FDA-recognized standard to meet a requirement under the Act to which the standard is applicable. It also requires the manufacturer to maintain information demonstrating conformity. The manufacturer must have this information at the time a declaration is submitted and must provide the information to FDA upon request. Under Sections 301(x) and 501(e)(2), submitting a false declaration is a violation of the Act.

FDAMA also established requirements that support ODE’s traditional approach for the use of standards in making substantial equivalence determinations. FDAMA established Section 513(i)(1)(C) of the Act, which requires FDA to consider the extent to which reliance on postmarket controls may expedite substantial equivalence determinations. FDA’s use of routine postmarket inspections to confirm the existence of data demonstrating conformity with standards is consistent with Section 513(i)(1)(C). In addition, FDAMA created Section 513(i)(1)(D), which requires FDA to consider the least burdensome means of demonstrating substantial equivalence and to request information accordingly. ODE’s acceptance of

Regulation (QSR) to maintain records that list the specifications for a device and demonstrate that it has been manufactured in accordance with its specifications. These records are subject to FDA inspection. In addition, manufacturers of Class II, Class III, and certain Class I devices (i.e., the vast majority of devices that are subject to 510(k)) are required by the design controls provisions of the QSR (21 CFR 820.30) to establish verification and validation procedures that confirm a device has fulfilled its design requirements (such as performance standards), and to maintain records of these activities. These records also are subject to FDA inspection.

descriptive specifications and statements about conformity to standards in making substantial equivalence determinations, rather than always requiring data from tests of final production units, is supported by Section 513(i)(1)(D).

Procedures

As a result of FDAMA, there are now three main ways in which manufacturers may elect to use standards in demonstrating substantial equivalence in 510(k)s.⁵ These uses of standards and ODE's review procedures are discussed below.

A. Use of FDA-Recognized Standards With a Declaration of Conformity Under Section 514(c)

Manufacturers may elect to conform to an FDA-recognized standard and to include a declaration of conformity in a 510(k). Manufacturers using this approach may benefit from the certainty of knowing that FDA is legally bound to accept the declaration to meet requirements of the Act to which the standard is applicable. FDA's recognition of the standard signifies that FDA is familiar with the standard and believes it is appropriate for meeting relevant premarket requirements. ODE reviewers should evaluate 510(k)s that contain a declaration of conformity in accordance with the Center's guidance documents related to this approach. (See "Recognition and Use of Consensus Standards," February 19, 1998, and "[The New 510\(k\) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications](#)," March 20, 1998.) In essence, this means that ODE reviewers should:

- Ensure that the standard is applicable to the device for which the 510(k) was submitted. Normally, if an FDA-recognized standard is applicable to a device, the device will be identified in the standard's Supplemental Information Sheet on the Center's website that lists FDA-recognized standards (<http://www.fda.gov/cdrh/modact/recstand.html>). If the device for which a 510(k) was submitted is not identified in the Supplemental Information Sheet, then the reviewer should recommend an appropriate course of action through their supervisor to the decision making official for 510(k)s, i.e., the Division Director. The Division Director will decide whether the declaration of conformity is appropriate for the previously unidentified device.
- Determine the extent to which the standard addresses 510(k) information needs. Reviewers should accept a declaration of conformity to meet 510(k) requirements to which the standard is applicable, and normally should not require that the 510(k) contain information demonstrating conformity to the standard. (Section 514(c) requires that this information exist in the manufacturer's files at the time a declaration of conformity is submitted to the agency.)

⁵ In the next revision of "[The New 510\(k\) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications](#)," March 20, 1998, the Center plans to expand the meaning of "Abbreviated 510(k)" to include all three of these approaches.

- Consult with their immediate supervisor and the Division Director before requesting additional information in the rare instances when reviewers have specific concerns about the adequacy of a recognized standard for a device aspect purportedly covered by the standard, as specified in the “Recognition and Use of Consensus Standards” guidance cited above.
- Ensure that the declaration of conformity contains the appropriate content, as specified in the “Recognition and Use of Consensus Standards” guidance.
- Ensure that all 510(k) requirements that the standard does not address are satisfied.
- Clearly indicate in their review memorandum that a declaration was provided and relied upon, specifying the 510(k) requirements that the standard addressed.

B. Use of FDA-Recognized Standards Without a Declaration of Conformity

Manufacturers may include a statement in a 510(k) that a device conforms (or will conform before marketing) to an FDA-recognized standard, without submitting a declaration of conformity. This is the pre-FDAMA approach discussed earlier in this memorandum, except that the approach is strengthened by the use of an FDA-recognized standard. FDA’s recognition signifies that FDA is familiar with the standard and believes it can be used to meet 510(k) requirements, to the extent addressed by the standard. ODE’s basis for relying on the statement is the same as it was before enactment of Section 514(c).

ODE reviewers should follow essentially the same review procedures for 510(k)s containing statements as for 510(k)s containing a declaration of conformity. In particular, reviewers should routinely accept a statement about conformity with an FDA-recognized standard to meet relevant 510(k) requirements and not require the submission of information demonstrating conformity with the standard. (Manufacturers must have information demonstrating conformity before they market the device, and these records will be subject to FDA inspection under a compliance program to assess conformance to the quality systems regulation.) While the 510(k) will not contain a declaration of conformity, reviewers should ensure that the submission provides sufficient information to identify the version of the standard and the specific provisions with which the manufacturer intends to conform. Reviewers should clearly indicate in their review memorandum that a statement about conformity with an FDA-recognized standard was provided and relied upon, and should specify the 510(k) requirements that the standard addressed.

C. Use of Non-Recognized Standards

A manufacturer may elect to conform to a standard that is not yet recognized by FDA, as noted in FDA’s question and answer document on recognition of standards. (See [“Guidance on Frequently Asked Questions on Recognition of Consensus Standards,”](#) December 21, 1998.) Unlike recognized standards, however, there is less assurance that a non-recognized standard will be acceptable in meeting 510(k) requirements.

If a 510(k) contains a statement that a device conforms (or will conform before marketing) to a non-recognized standard, and ODE previously has accepted such statements for this standard in meeting relevant 510(k) requirements, ODE reviewers should continue to do so. In this case, reviewers should process the 510(k) in accordance with the procedures (discussed above) for the use of FDA-recognized standards without a declaration of conformity. If a 510(k) refers to a non-recognized standard for which ODE has not previously relied upon a statement about conformity, reviewers should assess, before relying on the standard, whether the standard adequately addresses the substantial equivalence issues to which it is being applied. Depending upon factors such as ODE's familiarity with the standard and the specificity of the standard, reviewers may need to request information about the standard, how the device conformed to it, or a justification for its use in meeting 510(k) requirements. As with FDA-recognized standards, reviewers should clearly indicate in their review memorandum if a statement about conformity with a non-recognized standard was used in meeting 510(k) requirements.

After accepting a justification for relying on a non-recognized standard, ODE reviewers should take steps, if appropriate, toward FDA's recognition of the standard, as discussed in the guidance document entitled, "CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition," August 6, 1999.

Summary

FDA's recognition of more than 400 standards under the new authority provided by Section 514(c) of the Act has strengthened opportunities for the use of standards in making substantial equivalence determinations. Recognition signifies that FDA is familiar with the standard and believes it is appropriate for meeting relevant premarket requirements. Manufacturers may use FDA-recognized standards to meet 510(k) requirements in either of two ways: (1) by submitting a declaration of conformity; or (2) by submitting a statement. The first approach requires manufacturers to have supporting data in their files at the time a 510(k) is submitted, while the second approach requires manufacturers to have such data before a device is marketed. Under either approach, ODE reviewers normally should accept the declaration/statement in meeting relevant 510(k) requirements, and normally should not require the submission of information demonstrating conformity with the standard. This is in keeping with Section 514(c) (for declarations) as well as the "least burdensome" provisions of Section 513(i)(1)(D). Manufacturers may also use non-recognized standards to meet relevant 510(k) requirements, though there is less assurance that these standards will be acceptable. Depending upon factors such as ODE's familiarity with the standard and its specificity, reviewers may need information beyond a statement to support reliance on the standard.

Effective Date

This guidance document is effective immediately.