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Surgical Sutures – Performance Criteria for Safety and Performance Based Pathway

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Guidance for Industry and Food and Drug Administration Staff

GUIDANCE

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For questions about this document, contact the DHT4B: Division of Infection Control and Plastic and Reconstructive Surgery at 301-796-6891.



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

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2022-D-0552. Comments may not be acted upon by the Agency until the document is next revised or updated.

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance provides performance criteria for surgical sutures in support of the Safety and Performance Based Pathway.[1] Under this framework, submitters (you) planning to submit a 510(k) using the Safety and Performance Based Pathway for surgical sutures will have the option to use the performance criteria provided in this guidance to support substantial equivalence, rather than a direct comparison of the performance of the subject device to that of a predicate device.

For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.[3]

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (section 701(h)(1)(C)(i) of the FD&C Act and 21 CFR 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. This guidance document

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway
[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

In September 2019, FDA issued a guidance to describe an optional pathway – the Safety and Performance Based Pathway[4] – for certain, well understood device types, where a submitter could demonstrate that a new device meets FDA-identified performance criteria to demonstrate that the device is as safe and effective as a legally marketed device. In order to identify the specific set of performance criteria appropriate to satisfy a submitter's comparison to an appropriate predicate for a given device-type, FDA has determined that the performance criteria represent performance that meets the performance of one or more existing, legally marketed devices of that device type. Specifically, FDA relied on the experience and expertise of FDA staff, information in literature, and analyses of data available to FDA on legally marketed surgical sutures to determine the performance criteria and associated testing methods that could support a finding of substantial equivalence for surgical sutures as described in this guidance. FDA recognizes that in some cases, it may be more burdensome for a submitter to conduct testing against an appropriate predicate device to demonstrate equivalence for the necessary set of performance and technological characteristics than to demonstrate their device meets appropriate performance criteria established by FDA. Accordingly, we concluded that the optional device-specific Safety and Performance Based Pathway utilizing the performance criteria identified in this guidance provides a less burdensome policy consistent with the public health.

III. Scope/Device Description

The surgical sutures that are the subject of this guidance are absorbable and nonabsorbable sutures under the following regulations and product codes outlined in Table 1. These devices are Class II and are intended for the approximation and/or ligation of soft tissue.

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

Table 1: Surgical Sutures That Are the Subject of This Guidance

Regulation Name	Regulation	Product Code
Absorbable Polydioxanone Surgical (PDS) Suture	21 CFR 878.4840	NEW
Absorbable Poly(glycolide/L-lactide) Surgical Suture	21 CFR 878.4493	GAM
Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture	21 CFR 878.5000	GAT
Nonabsorbable Polypropylene Surgical Suture	21 CFR 878.5010	GAW, MXW
Nonabsorbable Polyamide Surgical Suture	21 CFR 878.5020	GAR
Natural Nonabsorbable Silk Surgical Suture	21 CFR 878.5030	GAP
Stainless Steel Suture	21 CFR 878.4495	GAQ, NJU
Nonabsorbable Expanded Polytetrafluoroethylene (ePTFE) Surgical Suture	21 CFR 878.5035	NBY

The following types of surgical sutures are outside the scope of this guidance:

- Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology (21 CFR 878.4494, NWJ)
- Nonabsorbable expanded polytetrafluoroethylene surgical suture for chordae tendinae repair or replacement (21 CFR 878.5035, PAW)
- Absorbable surgical gut suture (21 CFR 878.4830, GAL)

Intended Use/Indications for Use:
The surgical sutures that fall within the scope of this guidance document are intended for general soft tissue approximation and/or ligation, such as use in ophthalmic, cardiovascular, neurological, orthopedic, and dental procedures. For example, stainless steel sutures indicated for soft tissue approximation, abdominal wound closure, hernia repair, sternal closure and certain orthopedic procedures, including cerclage and tendon repair, would be within the scope of this guidance.

Surgical sutures that fall outside the scope of this guidance document include those intended for more specific uses than those identified in the regulations in Table 1 above (e.g., sutures intended for aesthetic uses or specialized cardiovascular applications).

Device Design and Other Characteristics:
Non-absorbable sutures are described as a multifilament or monofilament, non-absorbable, sterile, flexible, metallic, natural or polymeric thread intended for uses such as soft tissue approximation and ligation, abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure. It may be coated or uncoated, undyed or dyed with an approved color additive,[5] and provided with or without an attached needle(s).

[5] See "Summary of Color Additives for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices" at https://www.fda.gov/industry/color-additive-inventories/summary-color-additives-use-united-states-foods-drugs-cosmetics-and-medical-devices for more information

Absorbable sutures are described as a multifilament or monofilament, absorbable, sterile, flexible, synthetic thread intended for soft tissue approximation and ligation. It may be coated or uncoated, undyed or dyed with an approved color additive, and provided with or without an attached needle(s).

Surgical sutures within the scope of this guidance must meet the requirements of 21 CFR 70.5(c) regarding the use of color additives in sutures.

Surgical sutures with the following types of characteristics are outside the scope of this guidance:

- Sutures comprised of materials other than those listed in Table 1.
- Sutures comprised of animal-derived materials.
- Sutures that contain a drug or biologic.
- Sutures with atypical design features, including barbs, loops, anchors, knots, unique braiding patterns (e.g., suture tapes, braids containing an expandable core), sutures supplied with specialized delivery tools, including hollow needles or cannulas (i.e., non-swaged needles), and other design features that would necessitate performance evaluation outside the scope of this guidance.
- Surgical sutures that contain a color additive not already approved for use in the specific suture material.
- Sutures sterilized using novel sterilization methods as described in FDA's guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.[6]

Some of the recommendations in this safety and performance guidance may assist in complying with some of the special controls for surgical sutures. For information regarding the special controls for surgical sutures, see "Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff."[7]

FDA may determine, on a case-by-case basis, that additional data are necessary to evaluate whether the device is appropriate for the Safety and Performance Based Pathway. In situations where you determine that additional testing outside of those identified in this guidance are necessary to determine whether the device is appropriate for the Safety and Performance Based Pathway, we would encourage you to submit a Pre-Submission[8] to engage in discussion with FDA prior to submission of the 510(k).

IV. Testing Performance Criteria

If your device is appropriate for submission through the Safety and Performance Based Pathway, and you choose to use that option, we do not expect you to provide direct comparison testing

[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled

[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/class-ii-special-controls-guidance-document-surgical-sutures-guidance-industry-and-fda-staff

[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

against a legally marketed predicate device to demonstrate substantially equivalent performance characteristics. To ensure that the performance criteria outlined in this guidance remain contemporary and take into account relevant data from recent clearances, FDA recommends that you provide a results summary for all tests evaluated in addition to the other submission information (e.g., Declaration of Conformity (DoC)) recommended below for each test or evaluation below. Consistent with FDA policy for all 510(k) submissions, for all 510(k) submissions under the Safety and Performance Based Pathway, FDA may request and review underlying data demonstrating that a new device meets the FDA-identified performance criteria and testing methodology, as necessary. We recommend that all surgical sutures conform to the monographs and sections of the currently FDA-recognized edition of the USP, as identified below. Additionally, we recommend that you conduct all testing on the sterilized suture in finished form (e.g., needled, in reels) as per the Monograph for Nonabsorbable Sutures or as per the Monograph for Absorbable Sutures. Unless otherwise identified in the sections below, test information such as results summary, test protocols, and complete test reports should be submitted as part of the 510(k) as described in FDA's guidance Safety and Performance Based Pathway. For additional information regarding the submission of non-clinical bench testing information, refer to FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.[9]

1. **Test name:** Absorbable Suture Diameter (only for absorbable surgical sutures)
   Methodology: FDA-recognized version of USP 43-NF38 *<861> Sutures – Diameter*
   Performance Criteria: The average diameter, and no less than 20 of the 30 measurements on the 10-strand sample, are within the limits on average in Table 2 of USP 43-NF38 (2020) *Absorbable Surgical Suture* for synthetic sutures within the absorbable suture monograph for the size stated on the label. None of the individual observed measurements should be less than or greater than the limits on individual diameters in Table 2 of USP 43-NF38 (2020) *Absorbable Surgical Suture*.
   Performance Criteria Source: FDA-recognized version of USP 43-NF38 (2020) *Absorbable Surgical Suture*
   Sutures That Do Not Meet the Performance Criteria: If your suture does not meet USP requirements for diameter (e.g., oversize in diameter), it may still be appropriate for the Safety and Performance Based Pathway provided that the suture diameter is not oversized by more than 1 USP size (i.e., the maximum diameter for a given size is not more than the maximum individual limit on diameter for the next larger size). The labeling should clearly state that the suture is non-USP and should identify, for each suture size, the maximum oversize in diameter. This information can be presented as a table that identifies the USP size, associated USP diameter range, and maximum oversize for each proposed size.
   Submission Information: Results summary and DoC

2. **Test name:** Nonabsorbable Suture Diameter (only for nonabsorbable surgical sutures)
   Methodology: FDA-recognized version of USP 43-NF38 *<861> Sutures – Diameter*

[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

Performance Criteria: The average diameter, and no less than 20 of the 30 measurements on the 10-strand sample, are within the limits on average in Table 1 of USP 43-NF38 (2020) *Nonabsorbable Surgical Suture* for the size stated on the label. None of the individual observed measurements should be less than or greater than the limits on individual diameters in Table 1 of USP 43-NF38 (2020) *Nonabsorbable Surgical Suture*.
Performance Criteria Source: FDA-recognized version of USP 43-NF38 (2020) *Nonabsorbable Surgical Suture*
Sutures That Do Not Meet the Performance Criteria: If your suture does not meet USP requirements for diameter (e.g., oversize in diameter), it may still be appropriate for the Safety and Performance Based Pathway provided that the suture diameter is not oversized by more than 1 USP size (i.e., the maximum diameter for a given size is not more than the maximum individual limit on diameter for the next larger size). The labeling should clearly state that the suture is non-USP and should identify, for each suture size, the maximum oversize in diameter. This information can be presented as a table that identifies the USP size, associated limits on average diameter, and maximum oversize for each proposed size.
Submission Information: Results summary and DoC

3. **Test name:** Needle Attachment
   Methodology: FDA-recognized version of USP 43-NF38 *<871> Sutures – Needle Attachment*
   Performance Criteria: Neither the average of the 5 values nor any individual value is less than the limits given for the designated size in Table 1 of USP 43-NF38 *<871> Sutures – Needle Attachment*.
   Performance Criteria Source: FDA-recognized version of USP 43-NF38 (2020) *<871> Sutures – Needle Attachment*
   Submission Information: Results summary and DoC

4. **Test name:** Absorbable Suture Tensile Strength (only for absorbable surgical sutures)
   Methodology: FDA-recognized version of USP 43-NF38 *<881> Sutures – Tensile Strength*
   Performance Criteria: The average tensile strength is no less than that set forth in Table 2 of USP 43-NF38 (2020) *Absorbable Surgical Suture* for synthetic sutures within the absorbable suture monograph for the class and the size stated on the label.
   Performance Criteria Source: FDA-recognized version of USP 43-NF38 (2020) *Absorbable Surgical Suture*
   Submission Information: Results summary and DoC

5. **Test name:** Nonabsorbable Suture Tensile Strength (only for nonabsorbable surgical sutures)
   Methodology: FDA-recognized version of USP 43-NF38 *<881> Sutures – Tensile Strength*
   Performance Criteria: The average tensile strength is no less than that set forth in Table 1 of USP 43-NF38 (2020) *Nonabsorbable Surgical Suture* for the class and the size stated on the label.

Performance Criteria Source: FDA-recognized version of USP 43-NF38 (2020) *Nonabsorbable Surgical Suture*
Submission Information: Results summary and DoC

6. **Test name:** Resorption Profile (only for absorbable surgical sutures)
Methodology: The resorption profile testing should include information to document the device's rate of absorption, time to complete absorption, and residual tensile strength over time. The resorption profile should be presented in a chart, table, or graph that illustrates the residual tensile strength of the suture for a clinically significant period of time. The length of time considered clinically significant depends on the suture's intended use. We recommend that studies be performed *in vivo* using a model that appropriately replicates how and where the surgical suture is intended to be used. A significant number of sutures should be tested to demonstrate consistent tensile strength retention of the surgical suture. Additionally, testing should include at least the largest and smallest sizes of your suture, as well as sizes in between, skipping no more than two size differences between sizes tested. For example, if you intend to market all suture sizes from 7 to 7-0, we recommend that you test the sizes 7, 4, 1, 2-0, 5-0, and 7-0 for tensile strength retention. For additional information, see the special controls document "Surgical Sutures – Class II Special Controls Guidance for Industry and FDA Staff."
Performance Criteria: The device has a resorption profile that is consistent with the intended use of the device (e.g., short-term or long-term approximation of soft tissue).
Performance Criteria Source: Surgical Sutures – Class II Special Controls Guidance for Industry and FDA Staff
Submission Information: Results summary and testing protocol

7. **Test name:** Sterilization (for devices labeled as sterile)
Methodology: Current FDA-recognized version of the following consensus standards (as applicable):
    - ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*
    - ISO 11135-1 *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
    - ISO 11137-1 *Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
    - ISO 20857 *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*
    - ISO 11607-1 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*
    - ISO 11607-2 *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*

Performance Criteria: Validation testing should demonstrate the sterility of, or the ability to sterilize to a sterility assurance level of 10^{-6} for, the device.

Performance Criteria Source: FDA's guidance:

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile[10]

Submission Information: You should provide a description of the packaging (sterile barrier system) and how it will maintain the device's sterility, and a description of the package test methods, but not package test data. With respect to the Established Sterilization Method, whether using an Established Category A or Established Category B sterilization method, you should provide the information in Section V.A. of the FDA guidance Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile; generally, the validation data itself is not needed to demonstrate substantial equivalence.

8. **Test name:** Shelf Life
Methodology: Shelf life studies should evaluate the critical device properties to ensure the device will perform adequately and consistently during the entire proposed shelf life. You should follow performance testing methods outlined in Tests #1-7 above (as applicable) using aged versions of the suture. Testing should be performed on at least three (3) production lots of devices aged according to the proposed shelf life.
Performance Criteria: To demonstrate continued sterility, package integrity, and device functionality over the labeled shelf life, the aged versions of the suture should meet the respective performance criteria outlined in Tests #1-7 above (as applicable).
Performance Criteria Source: See performance criteria sources for Tests #1-7 above.
Additional Considerations: If you use devices subject to accelerated aging for shelf life testing, we recommend that you specify the way in which the devices were aged. We recommend that you age your devices as per the current FDA-recognized version of ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* and specify the environmental parameters established to attain the expiration date. For sutures containing polymeric materials, you should plan to conduct testing on real-time aged samples to confirm that the accelerated aging is reflective of real-time aging.
Submission Information: See "Submission Information" sections for Tests #1-7 above. We recommend that you provide a summary of the test methods used for your shelf life testing, results and the conclusions drawn from your results.

Biocompatibility Evaluation

To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation, you should use Attachment A of the FDA guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,"[11] referred to in the rest of this document as the FDA Biocompatibility Guidance for brevity. The contact type and duration for surgical sutures will depend on the

[10] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled
[11] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and

intended use. FDA considers surgical sutures to be implant devices in contact with tissue/bone, as well as blood in some cases, for a prolonged or permanent contact duration, as described in ISO 10993-1 and Attachment A of the FDA Biocompatibility Guidance. For a prolonged or permanent contact duration suture in contact with tissue/bone, the following endpoints should be addressed in your biocompatibility evaluation.

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute systemic toxicity
- Material-Mediated Pyrogenicity
- Subacute/Subchronic Toxicity
- Genotoxicity
- Clinically-relevant implantation
- Chronic Toxicity
- Carcinogenicity

Additional endpoints for prolonged or permanent contact duration sutures in contact with blood include:

- Hemocompatibility

Rationale in Lieu of Testing: If the subject device is manufactured from the identical raw materials using identical manufacturing processes as a predicate device with the same type and duration of tissue contact, and any changes in geometry are not expected to impact the biological response, this is typically sufficient to establish substantially equivalent biocompatibility, if documentation such as that outlined in Attachment F of the FDA Biocompatibility Guidance is also provided.

Testing: If you determined that testing is needed to address some or all of the identified endpoints, FDA recommends that complete test reports be provided for all tests performed unless a declaration of conformity without supplemental information can be appropriately provided, as discussed in Attachment E of the FDA Biocompatibility Guidance. Any test-specific positive, negative, and/or reagent controls should perform as expected, and protocol deviations should be thoroughly described and justified; however, note that certain protocol deviations may invalidate comparison to the performance criteria listed below. As described in the FDA guidance, Safety and Performance Based Pathway,[12] if a device cannot rely entirely on performance criteria identified by FDA to demonstrate substantial equivalence for its submission, it is not appropriate for the Safety and Performance Based Pathway program; however, the previously established 510(k) programs in which direct performance comparisons against appropriate predicates are conducted, including Traditional, Special, and Abbreviated 510(k)s, remain available.

9. **Test name:** Biocompatibility endpoints (identified from FDA Biocompatibility Guidance)

[12] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

Methodology: Current FDA-recognized versions of biocompatibility consensus standards
Performance Criteria: All direct tissue contacting components of the device should be determined to have an acceptable biological response.
Performance Criteria Source: The FDA Biocompatibility Guidance
Additional Considerations: For any biocompatibility test samples with an adverse biological response, the biocompatibility evaluation should explain why the level of toxicity seen is acceptable. Some comparison testing against a legally marketed predicate may be necessary (and is considered appropriate under the Safety and Performance Based Pathway) to support such a rationale as explained in the FDA Biocompatibility Guidance. For standard biocompatibility test methods that include comparison device control samples, the legally marketed comparison device control samples should perform as expected.

For surgical sutures supplied with needles, you should cite conformance to an FDA-recognized standard (e.g., for stainless steel) and provide a justification for why biocompatibility testing is not needed for the needle. If you are unable to cite conformance to a recognized standard and/or if your needle is coated, biocompatibility testing should be conducted on the needle component in accordance with ISO 10993-1 for the appropriate contact classification – e.g., external communicating device with limited contact duration (< 24 hours).
Submission Information: Refer to FDA Biocompatibility Guidance