U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us

We'll get started in a few minutes

Today's Topic:

Case Study: Material Substitutions in Devices Subject to Premarket Notification [510(k)] Using Polytetrafluoroethylene (PTFE)

December 10, 2025

Case Study: Material Substitutions in Devices Subject to Premarket Notification [510(k)] Using Polytetrafluoroethylene (PTFE)

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Final Guidance

- **Deciding When to Submit a 510(k) for a Change to an Existing Device**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device
  - Issued October 25, 2017
  - Hereafter referred to as the “Mods Guidance”

Learning Objectives

- Understand PTFE supply issues relating to medical device manufacture
- Understand how to use the 510(k) Mods Guidance for material changes to an existing device
- Understand how to apply the 510(k) Mods Guidance principles to PTFE-to-PTFE substitutions

PTFE Material Landscape

PTFE in Medical Devices

- Fluoropolymers and short chain PFAS are broadly used in MedTech
  - Fluoropolymers as materials of construction
  - Other PFAS as processing aids (such as PTFE tape)
- Many fluoropolymer manufacturers are exiting the market, inducing stress in the current supply chain
  - Many medical device manufacturers and processors need to find substitutes
- FDA Webpage: PFAS in Medical Devices
  - www.fda.gov/medical-devices/products-and-medical-procedures/pfas-medical-devices

PTFE in Medical Devices

- Material Substitution can be complicated:
  - Is a functional substitute available?
  - Does it work in my process?
  - Do I need to revalidate manufacture?
  - Does the device still meet product specifications, or do I need to do a partial redesign?
  - Do I need to submit anything to the FDA to keep my device on the market?

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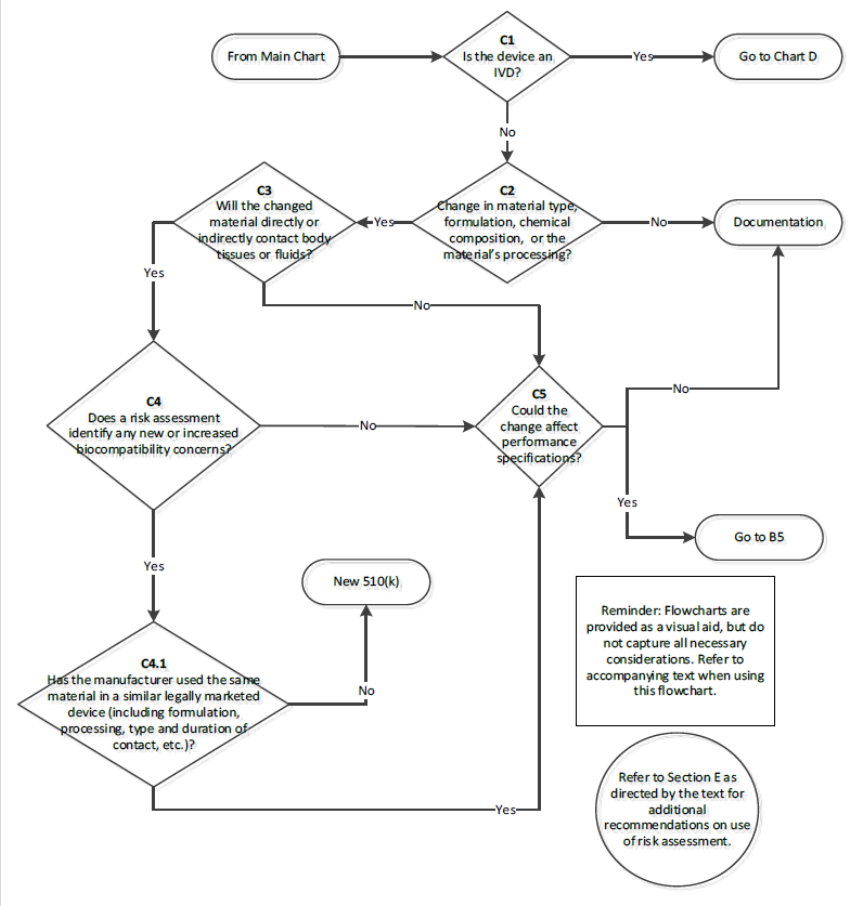
“The Mods Guidance” or Deciding When to Submit a 510(k) for a Change to an Existing Device

www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device

Assessing a Materials Change

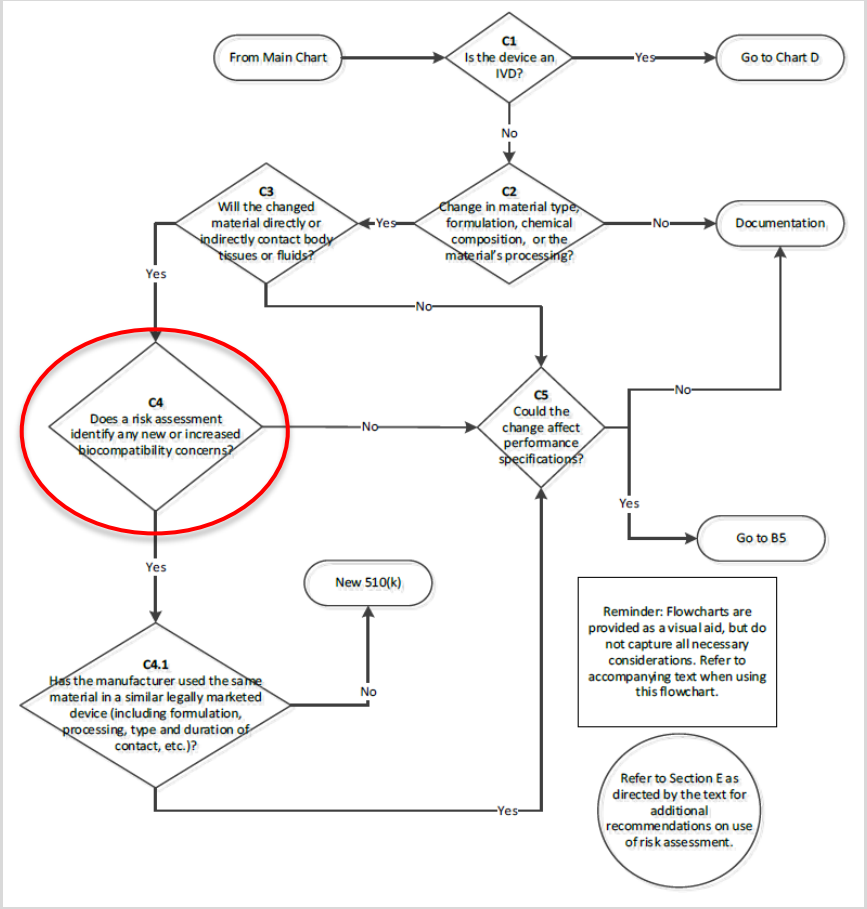


C1. Is the device an in vitro diagnostic (IVD)?

C2. Change in material type, formulation, chemical composition, or the material's processing?

C3. Will the changed material directly or indirectly contact body tissues or fluids?

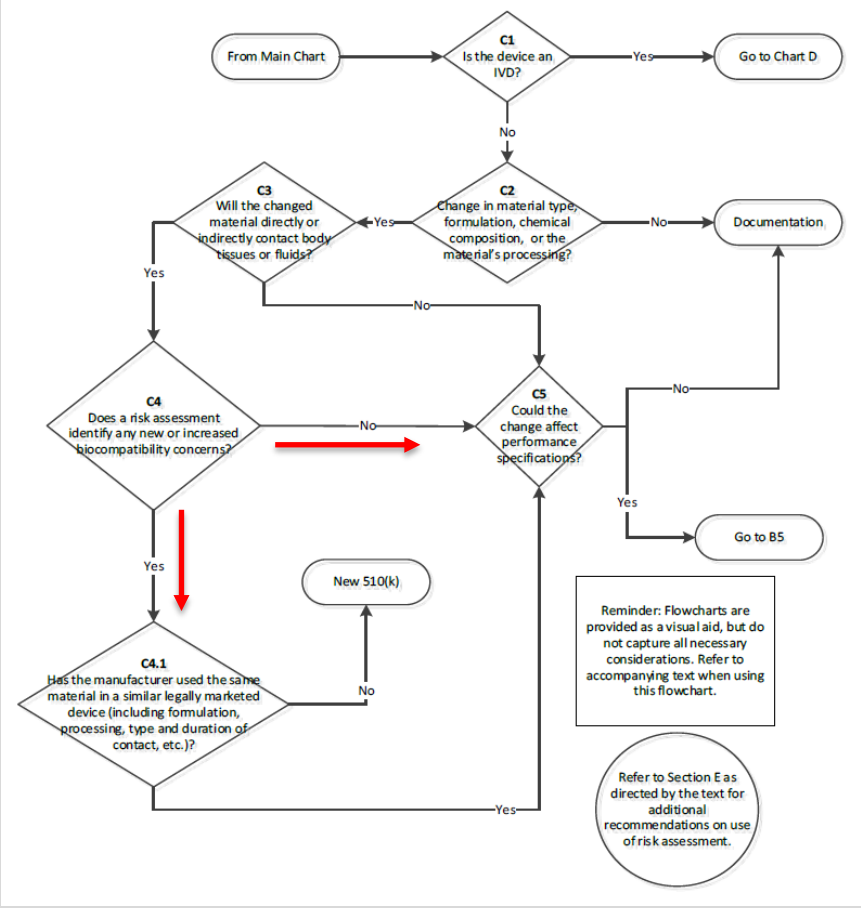
Assessing a Materials Change



C4. Does a risk assessment identify any new or increased biocompatibility concerns?

- "The answer may be no if a knowledgeable individual reviews the differences in chemical composition or physical properties and determines that the change is minor enough that there is no new concern about biocompatibility."

Assessing a Materials Change



C4.1. Has the manufacturer used the same material in a similar legally marketed device?

C5. Could the change affect the device's performance specifications?

- Examples of changes in materials are given in the guidance (#23 - #27)

Appendix B: Internal Documentation Recommendations

- Product name
- Date of change assessment
- Device description
- Reason why the change(s) is being made
- Applicable regulatory history, including the 510(k) number of the most recently cleared version of the device
- Comparison of the modified device to the most recently cleared version of the device (consider including a table)

Appendix B: Internal Documentation Recommendations

- Applicable elements of the 510(k) Mods Guidance, including the applicable questions from the body of the guidance
- Analysis and assessment of the elements on this list and a conclusion of whether submission of a new 510(k) is required
- Reference to related documents, particularly those that support the decision whether or not submission of a new 510(k) is required (such as risk analysis)
- Signature

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Section E. Risk Assessment (1)

- FDA recommends using an accepted risk assessment method (such as ISO 14971)
  - "It is not necessary to focus on hypothetical risks that are not supported by scientific evidence or those that are determined to be negligible due to both the low probability of occurrence and low severity of harm"
  - "If it's determined that the likelihood of a harm occurring due to a device change is negligible, then that change is unlikely to require submission of a new 510(k)"

ISO = International Standards Organization

Case Study with PTFE

- My Class 2 device has PTFE as a material of construction.
- The PTFE supplier has exited the market and I have sourced a substitute which has comparable material and processing properties.
- Manufacture of the device with the substitute produces device which meets the same specifications as prior to the substitution
  - Conduct risk analysis as per ISO 14971 or other process
  - From the 510(k) Mods Guidance, Flowchart C: Materials Changes
    - C4. New or increased biocompatibility concerns? **No, based on risk analysis**
    - C5. Could the change affect performance? **No. Product specifications have not changed and the device still meets specifications.**
- Document the change as per 510(k) Mods Guidance (“Letter to File”)

Resources

Cited Resource	URL
Deciding When to Submit a 510(k) for a Change to an Existing Device	www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device
PFAS in Medical Devices webpage	www.fda.gov/medical-devices/products-and-medical-procedures/pfas-medical-devices
CDRHLearn Postmarket Activities	www.fda.gov/training-and-continuing-education/cdrh-learn?utm_medium=email&utm_source=govdelivery

Summary

- Some fluoropolymer manufacturers have exited the market and you may be faced with needing a supplier or material change
- You can use the 510(k) Mods Guidance when assessing a material change to an existing device
- You can use the 510(k) Mods Guidance when assessing PTFE grade and/or manufacturer changes to existing devices


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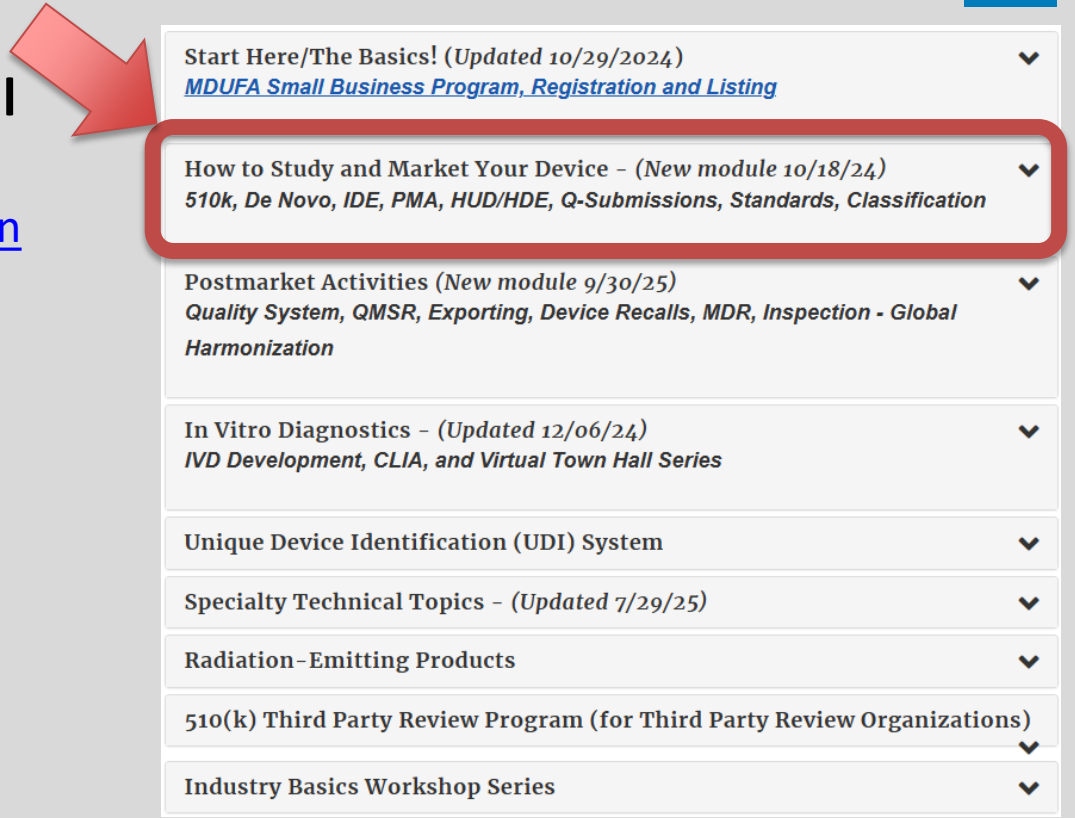
Panel Discussion

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**
  - www.fda.gov/Training/CDRHLearn
- **Additional questions about today's webinar**
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
  - www.fda.gov/CDRHEvents

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