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Safety and Performance Based Pathway Criteria for Certain Device Types

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Agenda

- Objectives
- Background
- Device-specific performance criteria final guidances
- 510(k) submission to Safety and Performance Based Pathway
- Future plans
- Opportunities for stakeholder engagement
- Q&A

Objectives

- Provide an overview of recently issued device-specific final guidances and how to use them
- Outline operationalization of Safety and Performance (S&P) Based Pathway

Timeline

- February 2019 – Safety and Performance Based Pathway final guidance issued
- September 2019 – First 4 device-specific draft* guidances issued
- November 2019 – [Safety and Performance Based Pathway Framework Webinar](#)
- December 2019 – Magnetic Resonance Coil Performance Criteria draft* guidance issued
- February 2020 – Soft (Hydrophilic) Daily Wear Contact Lenses draft* guidance issued
- August 2020 – First 2 device-specific final guidances issued

*Draft guidance – Not for implementation purposes

Safety and Performance (S&P) Based Pathway

- Voluntary 510(k) pathway for well-understood Class II devices that meet specified performance criteria
- Device would meet FDA-identified performance criteria used to demonstrate substantial equivalence
- Direct and transparent approach to demonstrating the safety and effectiveness of low to moderate risk devices

Device-Specific Guidances

- Appropriate devices are identified with the scope of each guidance
 - Regulation, product code, indications for use, etc.
- Cross-cutting recommendations largely the same and consistent with previous subject guidance(s)
 - Biocompatibility, sterility, electrical safety, etc.
- Only **final** (not draft) device-specific guidances can be implemented for the S&P pathway
- Initial device-specific performance criteria for S&P pathway final guidances
 - [Conventional Foley Catheters](#)
 - [Cutaneous Electrodes for Recording Purposes](#)



Performance Criteria

- FDA intends to identify the performance criteria for each device type eligible for the S&P Pathway in guidance
- FDA intends to recommend testing methods where feasible
- FDA intends to ensure that criteria represent performance levels that are at least equivalent to the performance of legally marketed devices

Performance Criteria (cont.)

- Derived from multiple sources including:
 - FDA-recognized consensus standards
 - FDA guidance
 - Special Controls
 - Scientific literature
 - Historical 510(k) submission data
- Only performance criteria in FDA-recognized consensus standards that have been identified in FDA Safety and Performance Based Pathway device-specific guidance can be used in the S&P pathway

Device-Specific Final Guidance Example

Contains Nonbinding Recommendations

Conventional Foley Catheters – Performance Criteria for Safety and Performance Based Pathway

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 14, 2020.

The draft of this document was issued on September 19, 2019

For questions about this document, contact the DHT3B: Division of Reproductive, Gynecology and Urology Devices at 301-796-7030.



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

Example – Foley Catheter Scope

II. Scope/Device Description

The Foley catheters that are the subject of this guidance are intended for the drainage and/or irrigation of the urinary tract. These devices are Class II and are regulated under 21 CFR 876.5130 with the product code EZL (Catheter, Retention Type, Balloon).

Intended Use/Indications for Use:

Drainage is accomplished by inserting the catheter through the urethra into the bladder. The catheter is retained by the use of a balloon inflated in the bladder, which is attached to the distal end of the catheter. The devices are single-use and indwelling time should be 30 days or less.

Device Design Characteristics:

The French sizes within the scope of this guidance include sizes 12 through 26 with a retention balloon volume no greater than 30 cm³. Two lumen catheters are included within the scope of this guidance. Three lumen catheters, catheters treated to enhance their lubricity, suprapubic catheters, and antimicrobial catheters are outside the scope of this guidance.

Example – Foley Catheter Performance Test

2. Test name: Flow Rate

Methodology: ASTM F623 *Standard Performance Specifications for Foley Catheters*

Performance Criteria: Catheters with French size 14-26 should have a minimum average flow rate of 100 cm³/min. French size 12 catheters should have a minimum average flow rate of 70 cm³/min.

Performance Criteria Source: ASTM F623 (2019) *Standard Performance Specifications for Foley Catheters*

Additional Considerations: ASTM F623 does not provide a criterion for French size 13 catheters as conventional Foley catheters typically have an even numbered French size.

Submission Information: Declaration of Conformity (DoC)

Example – Foley Catheter Biocompatibility

Biocompatibility Evaluation

To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation you should use Attachment A of CDRH's guidance [Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process](#), referred to in the rest of this document as the CDRH Biocompatibility Guidance for brevity. FDA considers the devices covered by this guidance to be categorized as “External Communicating Devices” with a “prolonged” tissue contact duration of >24 hours to 30 days and you should assess the endpoints below per Attachment A of the CDRH Biocompatibility Guidance.

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity (should be conducted to support devices labeled as “non-pyrogenic”)
- Sub-acute/Sub-chronic Toxicity
- Genotoxicity
- Implantation

Submitting 510(k): Is The Device Appropriate?

- New device should be within the scope of a device-specific performance criteria **final** guidance
- The new device meets all of the identified criteria
 - Unique to this pathway, all criteria must be met in order to be eligible
- Identification of an appropriate predicate is still necessary

Submitting 510(k): Are Performance Criteria Met?

- Performance criteria are appropriate when:
 - Indications and technical characteristics do not raise different questions of safety and effectiveness than the predicate
 - Performance criteria align with one or more predicates of the same device type
 - The new device meets all of the identified criteria

510(k) Submission to the S&P Pathway

- Same MDUFA 90 day review clock, like for Traditional and Abbreviated 510(k)
- Same MDUFA user fees
- Recommend cover letter state that the 510(k) submission is for the Safety and Performance Based Pathway

510(k) Submission to the Pathway (cont.)

- Refuse to Accept (RTA) similar to Abbreviated 510(k)
 - Consistent with [Refuse to Accept Policy for 510\(k\)s Guidance](#)
- Potential for conversion to Traditional 510(k)
- Substantive Interaction same as Traditional and Abbreviated 510(k)

Questions About The S&P Pathway?

- Pre-Submission
 - Can be used to determine if device is appropriate for the S&P Pathway
 - If otherwise in scope, can be used if you determine there is additional testing outside of the guidance that is necessary to demonstrate safety and performance of the device

Stakeholder Engagement

- Submit comments or suggestions
 - On device-specific guidances with device-specific feedback or general programmatic feedback
 - Device types well-suited for inclusion in S&P pathway to programmatic final guidance docket ([FDA-2018-D-1387](#))
 - Standardized methods and criteria for the FDA to evaluate

Resources

- [Safety and Performance Based Pathway webpage](#)
- [Safety and Performance Based Pathway final guidance](#)
- [November 2019 Safety and Performance Based Pathway webinar](#)
- [Recommended Content and Format of Non-clinical Bench Performance Testing Information in Premarket Submissions](#)
- [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)

Resources (cont.)

- Draft* Device-specific guidances
 - [Orthopedic Non-Spinal Metallic Bone Screws and Washers](#)
 - [Spinal Plating Systems](#)
 - [Magnetic Resonance \(MR\) Coils](#)
 - [Soft \(Hydrophilic\) Daily Wear Contact Lenses](#)
- Final device-specific guidances
 - [Conventional Foley Catheters](#)
 - [Cutaneous Electrodes for Recording Purposes](#)

*Draft guidance – Not for implementation purposes

Questions?

Division of Industry and Consumer Education: DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:

<http://www.fda.gov/training/cdrhlearn>

Under Heading: How to Study and Market Your Device; Subheading: Premarket Notification

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