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FDA/CDRH Webinar

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The 510(k) Program Guidance: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

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Background

• K86-3 Blue Book Memorandum “Guidance on the CDRH Premarket Notification Review Program, 510(k)” issued June 30, 1986
  – General discussion regarding the process of determining substantial equivalence between a new device and a predicate device.
  – Issued prior to FDA implementation of GGP

  – Introduced Special and Abbreviated 510(k) programs
  – Explains differences between Traditional, Special, and Abbreviated 510(k)s with respect to scope and submission content

• Neither document updated since initial publication
Background

  - Intended to offer greater clarity on topics discussed in K86-3 and The New 510(k) Paradigm guidance documents
  - Received over 400 comments
    - Special 510(k) technological characteristics, and predicate device sections received most comments
Response to Comments

• FDA carefully reviewed all comments and modified the draft guidance to address them

• Draft guidance revised to
  – more clearly explain the intent and value of the “primary predicate” concept
  – Include more examples to illustrate FDA’s decision making process
  – Include an appendix with a sample 510(k) Summary to demonstrate the level of detail expected in each section
Response to Comments

• Industry concern relating to the inclusion of Special 510(k) program section given the connection to deciding when to submit a new 510(k) for device modification

• In response, Special and Abbreviated 510(k) sections were removed
  – FDA intends to finalize these sections separately
  – The New 510(k) Paradigm Guidance remains in effect
Final Guidance

• FDA is announcing the availability of the guidance titled “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”
  – Describes FDA’s current review practices for 510(k) submissions by describing the regulatory framework, policies and underlying practices
  – Replaces K86-3 guidance
  – Issued in accordance with FDA’s GGP regulation (21 CFR 10.115)
Guidance Highlights

- Flowchart modification
- Discussion of new terms
- Illustrative examples for different NSE categories
- 510(k) Summary content explanation
Flowchart Modification

• Previously unmodified since introduction in K86-3
• Updated to incorporate statutory terminology
  – Language mirrors section 513(i) of the FD&C and 21 CFR 807.100
• Cosmetically reorganized
  – Increase clarity and visually streamlined
• Available in Appendix A
  – Not intended to be used as a stand-alone document
New Terms

• **Primary Predicate** - the identified predicate with indications and technology most similar to the subject device when multiple predicates are identified
  – can facilitate a timely review and well-supported decision

• **Reference Device** - a legally marketed device intended to provide scientific information to support safety and effectiveness.
  – Reference device is not a predicate and cannot be used to support decision points 1-4 on the Flowchart.

• Illustrative examples of each in guidance document

• Glossary of significant terminology in Appendix D
Illustrative Examples

- The NSE categories are unchanged
  - Lack of predicate
  - New intended use
  - Different questions of safety and effectiveness
  - Inadequate performance data
- Multiple examples of each NSE type described in guidance
- Discussion on intended use and indication for use
510(k) Summary

- Guidance includes additional discussion and examples on 510(k) Summary requirements and content

- Appendix B: discussion on 510(k) Summary document requirements
  - provides clarification to facilitate compliance with 510(k) Summary content requirements in 21 CFR 807.92
  - Each subpart of the regulation explained with suggested content

- Appendix C: sample of compliant 510(k) Summary
  - Intended to provide an example of the format and content expected
“The single biggest problem in communication is the illusion that it has taken place.”

-- George Bernard Shaw, Irish writer
Comments on this final guidance may be submitted at any time

- Electronic comments: [www.regulations.gov](http://www.regulations.gov)
Thank you for participating

Please send your questions to:
DICE@fda.hhs.gov

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