

# **Special and Abbreviated 510(k)s**

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## **Add-to files**

**510(k) Workshop  
April 21/22 - 2009**

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# Topics

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- What to do when changing or modifying a device
- What is a special 510(k)
- When to use a special 510(k)
- What to submit for a special 510(k)
- What is an abbreviated 510(k)
- What to submit for an abbreviated 510(k)
- What are the advantages/disadvantages of each
- When to use add-to file submission

# What to do when change or modification

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Device in commercial distribution but change or modification may significantly affect safety or effectiveness.

Guidance\* - Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)

flowchart model that can be used by manufacturers in their decision-making to analyze how changes in devices may affect safety or effectiveness

\* <http://www.fda.gov/cdrh/ode/510kmod.pdf>

# New 510(k)?

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510(k) holder – “Burger King”

decides if need new 510(k)

use FDA guidance

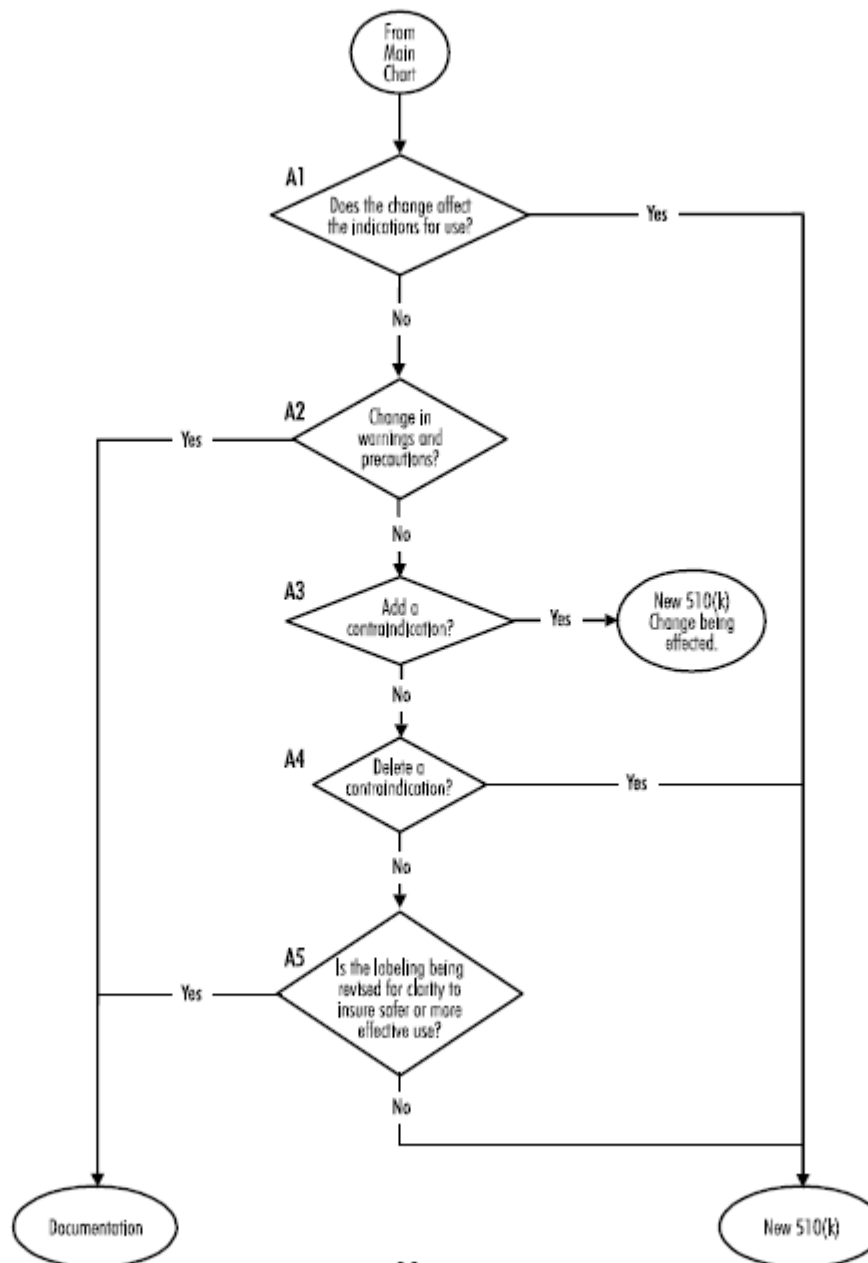
“Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)”

# Flowcharts

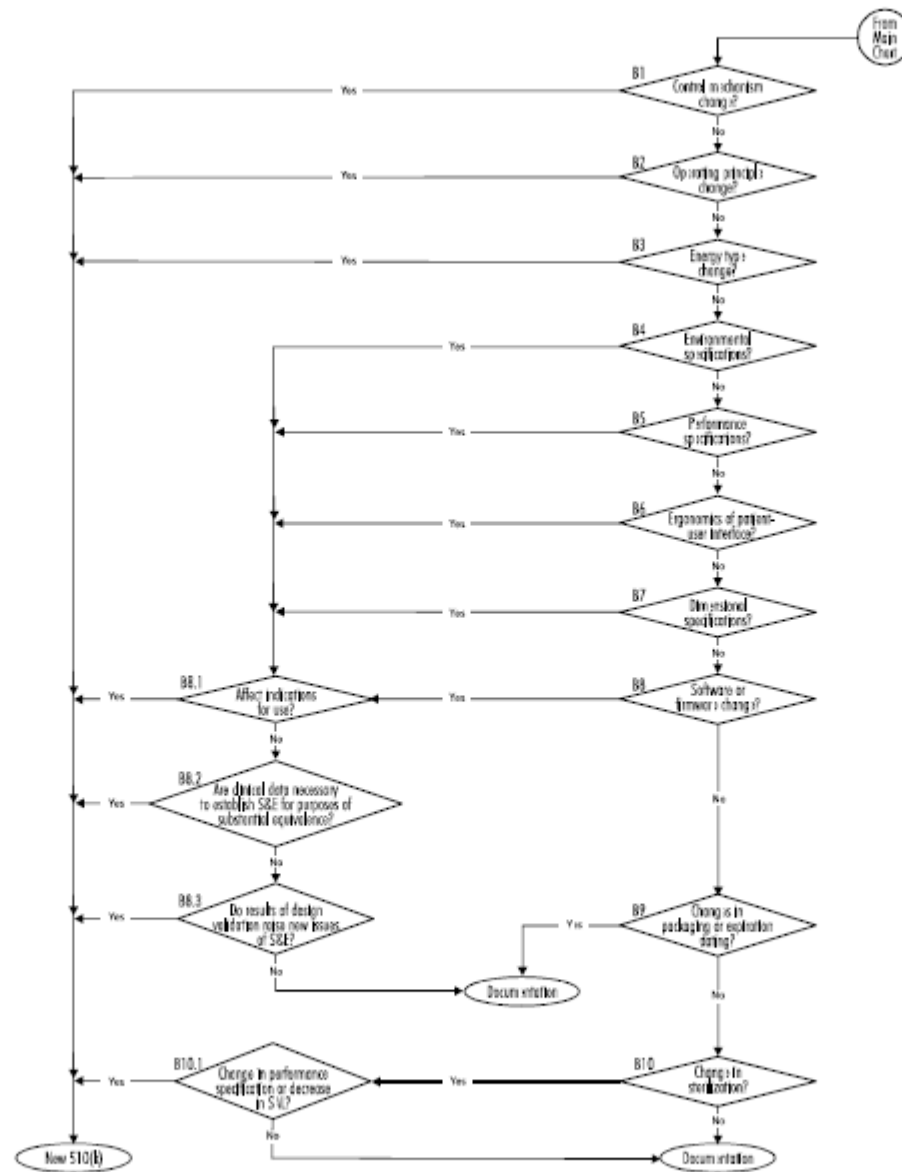
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- Main Flowchart
- Flowchart A - labeling changes
- Flowchart B - technology or performance specifications changes
- Flowchart C - materials changes
- Flowchart D - materials changes for *in vitro* devices (IVDs).

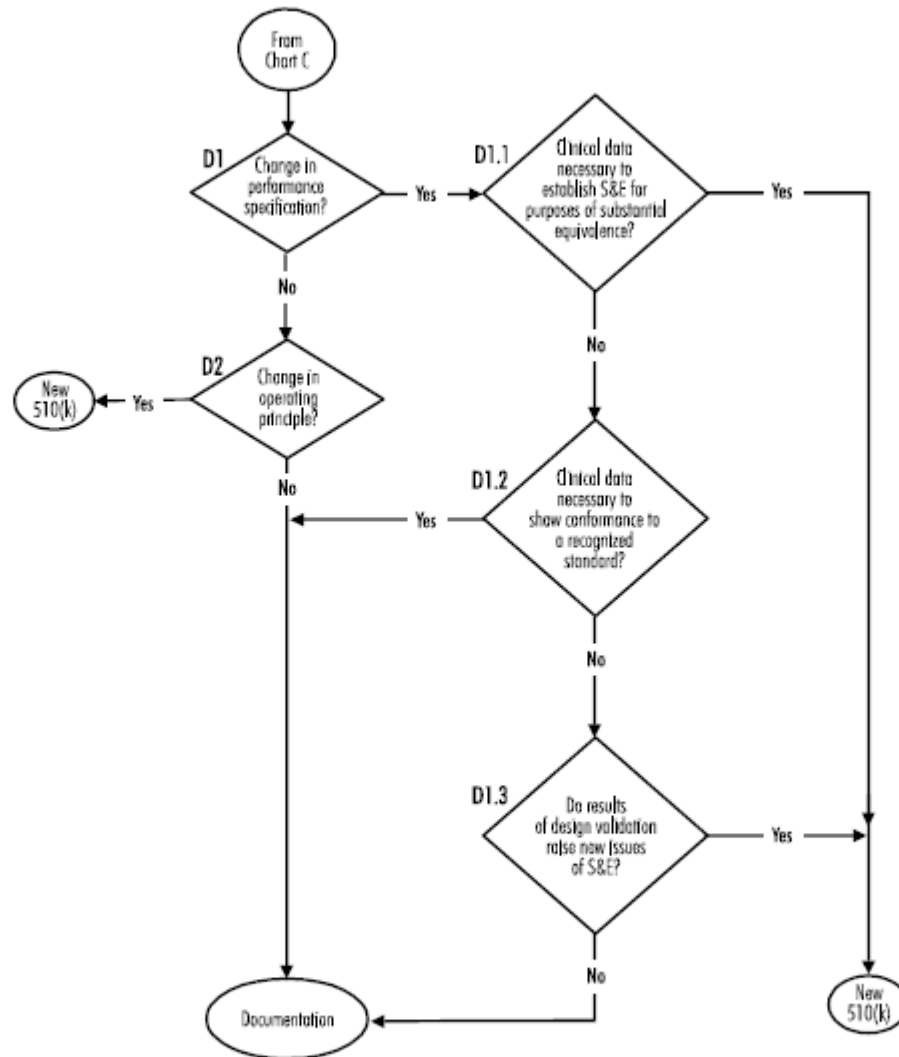
### FLOWCHART A - IS IT A LABELING CHANGE?



**FLOWCHART B - IS IT A TECHNOLOGY OR PERFORMANCE CHANGE?**



# FLOWCHART D - MATERIALS CHANGE FOR AN IVD



# New 510(k)? 5 Questions Flowchart D

## material change for IVDs

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1. Change in performance specifications? (cut-off, expected values, precision, interferences)
2. New clinical data (clinical samples) will be necessary to establish Safety and E?
3. New clinical data necessary to show continuing conformance of the device to a recognized standard? CRMLN, NGSP

# New 510(k)? 5 Questions

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4. Results of the design validation performed as a result of change in materials raise new issues of safety and effectiveness?
5. Change in material alter the operating principle of the IVD?

# New 510(k)? Answer yes

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3. New clinical data necessary to show continuing conformance of the device to a recognized standard? CRMLN, NGSP

# New 510(k)?

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If no:

- Any modifications must be made in accordance with the Quality System regulation, 21 CFR 820, and recorded in the device master record and change control records. Data available for FDA inspection.
- Keep justification for (not) submitting a new 510(k) in the change control records.
- **Do Not** Send “Add-to file” saying you made changes

# New 510(k)?

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- If yes, then –
- Special or traditional or abbreviated 510(k)?
- Change in intended use/indications for use or any labeling change that affects intended use?
- Change in fundamental scientific technology?
- Change requiring clinical study to evaluate patient safety and effectiveness?
  - No = special
  - Yes = traditional or abbreviated

# What is a special 510(k)

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- Utilizes the design control requirement of the Quality System Regulation (21 CFR 820)
- Application submitted for a modification to a device that has been cleared under the 510(k) process
- allows the manufacturer to declare conformance to design controls without providing the raw data

# Design Control Requirements

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- require the manufacturer to conduct verification and validation studies of a type that traditionally may have been included in 510(k) submissions
- may be appropriate to forgo a detailed review of the underlying data normally required in the 510(k) program.

# Changes - Special 510(k)

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- Change in reagent (dry to liquid)
- Change in ergonomics of patient user interface
- Change in expiration dating (not there)
- Change in manufacturing to produce reagents that do need calibration by user
- Add another anticoagulant as an acceptable sample

# Changes - Not a Special 510(k)

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- Change in intended/indications for use
- Change from prescription use to OTC
- Change in derivation of algorithm
- Change in major reactive ingredient that affects patient safety and effectiveness
- Change in cut-off that needs clinical study to assess patient safety and effect.
- Combining two cleared devices to make new
- Bundle modifications to devices in dif. 510(k)

# What to submit for special 510(k)

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- Medical Device User Fee Cover Sheet ([Form FDA 3601](#)). See [510\(k\) Review Fees](#) for additional information on review fees.
- CDRH Premarket Review Submission Cover Sheet [[PDF](#)] [[Word](#)] (recommended)
- Certification of Compliance with ClinicalTrials.gov Data Bank, [FDA-3674](#)\*
- \*Beginning December 26, 2007, all 510(k) submissions must include a completed copy of form FDA-3674. See [Form FDA-3674, ClinicalTrials.gov Data Bank](#) for additional information.

# What to submit for special 510(k)

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- Cover Letter, identifying the application as a "Special 510(k)." Include 510(k) holder name, address, and facility registration number, if available.
- Table of Contents
- 510(k) Screening Checklist (recommended)
- [Statement of Indications for Use](#) use OIVD form
- [510\(k\) Summary](#) [21 CFR 807.92] or [510\(k\) Statement](#) [21 CFR 807.93]
- Standards Data Report for 510(k)s - FDA 3654 [[PDF](#)] [[Word](#)]  
Submit this form if your 510(k) references a national or international standard.
- [Truthful and Accuracy Statement](#)

# What to submit for special 510(k)

- Detailed description of modified device
- Comparison to cleared device
- State no change in fundamental technology and no change in intended use
- Intended use of modified and cleared
- Proposed labels and labeling with all changes highlighted or prominently identified
- Summary of design control activities

# Summary of Design Control Activities

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- State risk analysis method used to assess the impact of the mod. (FMEA or FTA)
- Provide all verification/validations tests that were performed
- State pre-determined acceptance criteria
- Summary of results showing pre-determined acceptance criteria were met
- State pre-acceptance criteria were met

# Signed Declaration of Conformity with design control requirements

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- the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met
- The manufacturing facility, [*Company Name*] is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

# FDA Reviewer's Expectations for Special 510(k)

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- Required admin info for 510(k)
- Detailed description of the modified device
- Detailed comparison to the cleared device (similarities/differences) - operational principles

# FDA Reviewer's Expectations for Special 510(k)

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- Labeling is marked/highlighted with changes
- Intended use/indications for use of modified device and unmodified device
- Statement that no change in intended use/indications for use of the device
- Statement no change in fundamental tech
- Risk analysis method is identified

# FDA Reviewer's Expectations for Special 510(k)

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- Validation/verification activities similar to those in traditional 510(k) method comparison assay range studied, interference studies, etc.
- Pre-determined acceptance criteria appropriate for the clinical needs of assay
- Graphs and charts of data analyses clearly showing acceptance criteria were met and VV are complete

# Pre-determined acceptance criteria



## Appropriate or Inappropriate?

- Mean of three lots is within 10% of unmod
- Linearity is equivalent to unmod device
- Slope is within 0.95 to 1.05 and intercept is within 0.05 and -0.05
- Bias from all interferences is <10%
- 95% of results are within 10% of unmod.
- Average bias is < 10%

# Pre-determined acceptance criteria

## Appropriate or Inappropriate?

- Overall precision is  $< 10\%$
- Method comparison R value  $>.90$

# Advantages/Disadvantages of Special 510(k)

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- 30 days for decision by FDA
- Declare conformance to design control
- Most misunderstood type of submission
- Usually not clearly presented
- FDA does not understand the modifications
- Use of acceptance criteria not clinically relevant
- Summary of data not presented
- Acceptance criteria are not met

# What is an Abbreviated 510(k)

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- device-specific guidance documents
- special controls
- FDA recognized consensus standards\*

\*<http://www.fda.gov/cdrh/stdsprog.html>

# What is an Abbreviated 510(k)

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Need a summary report -

- Describes adherence to the relevant guidance or special control and
- How the guidance document was used during device development and testing
- Declaration of conformity if using standard

# Disadvantages of Abbreviated 510(k)s

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- One size does not fit all –
- Relatively few guidance documents to cover all aspects of IVD device performance
- No time advantage over traditional (90 FDA days)

# Advantages of Abbreviated 510(k)s

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- Calibrator materials
- Control materials
- De novos with special control guidance
- 124 submissions since June 1999

# What to Submit for Abbreviated 510(k)

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- All the common info for traditional
- Summary report
- Declaration of conformity to FDA consensus standard

# When to use an add-to file

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- Requesting CLIA categorization after using FDA guidance “Guidance for Industry and FDA Staff; Replacement Reagent and Instrument Family Policy”
- Submitting info for CLIA waiver
- Not for informing FDA about changes made to your device

# Helpful Websites

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**OIVD website:**

**<http://www.fda.gov/cdrh/oivd/index.html>**

**Device advice: How to prepare a special**

**<http://www.fda.gov/cdrh/devadvice/3144.html>**

**Device advice: How to prepare an abbrev.**

**<http://www.fda.gov/cdrh/devadvice/3145.html>**

**Recognition and use of consensus standards:**

**<http://www.fda.gov/cdrh/osel/guidance/321.html>**

# **Helpful Guidance Documents**

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**Deciding When to Submit a 510(k) for a  
Change to an Existing Device (K97-1)**

**<http://www.fda.gov/cdrh/ode/510kmod.pdf>**

**Guidance for Industry and FDA Staff**

**Format for Traditional and Abbreviated  
510(k)s -August 12, 2005**

**<http://www.fda.gov/cdrh/ode/guidance/1567.html>**

# Helpful Guidance Documents

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**Frequently Asked Questions on the New  
510(k) Paradigm – October 02, 1998**

**[http://www.fda.gov/cdrh/ode/92\\_a.html](http://www.fda.gov/cdrh/ode/92_a.html)**

**Guidance for Industry and FDA Staff  
Administrative Procedures for CLIA  
Categorization**

**<http://www.fda.gov/cdrh/oivd/guidance/1143.pdf>**

# **Helpful Guidance Documents**

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**Design Control Guidance For Medical  
Device Manufacturers – March 3, 1997**

**<http://www.fda.gov/cdrh/comp/designgd.html>**

**Guidance for Industry and FDA Staff;  
Replacement Reagent and Instrument  
Family Policy 12-11-2003**

**<http://www.fda.gov/cdrh/oivd/guidance/950.pdf>**

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Thank you!

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