Guidance for Industry

FREQUENTLY ASKED QUESTIONS ON THE NEW 510(k) PARADIGM

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

Program Operations Staff
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Heather Rosecrans at HFZ-404. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, contact Ms. Rosecrans at (301) 594-1190 or E-mail: hsr@cdr.fda.gov.

Additional Copies

Additional copies: World Wide Web/CDRH home page: http://www.fda.gov/cdrh/ode/qanda510k.pdf ,CDRH Facts on Demand at 1-800-899-0381, or (301)-827-0111, specify number 2230 when prompted for the document shelf number

FREQUENTLY ASKED QUESTIONS ON THE NEW 510(k) PARADIGM

On March 20, 1998, the Center for Devices and Radiological Health (CDRH) announced the availability of a guidance document entitled, "The New 510(k) Paradigm -- Alternatives to Demonstrating Substantial Equivalence in Premarket Notification Submissions." In this guidance, two new alternatives to the traditional approach of demonstrating substantial equivalence were discussed. Both alternatives, i.e., the Special 510(k) and the Abbreviated 510(k), were designed to provide flexibility to the device industry, conserve Agency and industry resources, and optimize the contribution of the 510(k) Program to the protection of public health.

Based on the Agency's and industry's experience with the Guidance, the Center has developed the following questions and answers. These should serve to clarify certain aspects of the document, specifically declarations of conformance to design controls and standards, and to promote consistency in the use of the Guidance. This question and answer document[1] will be updated on a periodic basis to include frequently asked questions and/or to provide the Agency's perspective on specific issues of the Paradigm. Interested persons can submit questions for inclusion in future revisions by calling Ms. Heather Rosecrans at (301) 594-1190 or submitting their questions via the Internet to hsr@cdrh.fda.gov.

At the end of this question and answer document, an example of a Special 510(k) for a cardiovascular catheter and a guidance document to be used in preparing an Abbreviated 510(k) for a latex condom can be found. These documents were developed with the aid of the regulated industry to help illustrate the two new alternatives to the Traditional 510(k). Comments on these examples are welcome and may be submitted to the above Internet address.

General Questions

1. **Are Special and Abbreviated 510(k)s eligible for review under the Agency's Third Party Pilot Program?**

   Both Special and Abbreviated 510(k)s may be reviewed under the Third Party Pilot Program as long as the 510(k)s are for devices that are included in that program. Given that the Agency has committed to a 30 day review of Special 510(k)s, however, there may be no real advantage to using Third Parties to review this particular type of submission.

[1] This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Note: Manufacturers should not confuse the review of select 510(k)s by Third Parties with third party involvement in assessing conformance with design controls or standards. This latter topic is discussed in more detail in response to question #4.

2. **Can FDA rely on a declaration of conformity for a substantial equivalence determination in an Abbreviated or Special 510(k) if the manufacturer states that they will conform rather than they are in conformance?**

The Food and Drug Administration Modernization Act of 1997 added section 514 (c*) Recognition of a Standard* to the Federal Food Drug and Cosmetic Act (the act). According to this section of the act, a declaration of conformity to a recognized standard must certify that the device is in conformance. Therefore, in order for the Center to rely upon a declaration of conformity to a standard in making a substantial equivalence (SE) determination in an Abbreviated 510(k), the declaration must indicate that the submitter is in conformance. The Agency has adopted this same approach for Special 510(k)s. That is, a manufacturer may not state that they will conform at some future date, but rather conformance must have already been determined at the time the application is submitted.

It should be noted that declarations indicating that a device/firm will conform to a standard/design controls has been the most common reason that a submission has not been accepted for review as either an Abbreviated or Special 510(k), respectively.

3. **What happens if an Abbreviated 510(k) includes a statement indicating that the device will conform but is not yet in conformance with a standard?**

As stated above, for issues material to the substantial equivalence determination, the Agency would not be able to rely upon such a statement. A declaration of conformity certifying that the device is in conformity to the standard would be needed.

The only exception to the above would be for cases where substantial equivalence had previously been demonstrated for devices of this type without conformance to the standard. For example, if a manufacturer states that a device will conform to IEC-60601-1-2 Electromagnetic Compatibility and substantial equivalence for the predicate device had been determined without conformance to the standard, then the submission could be reviewed as an Abbreviated 510(k). If, as stated above, conformance to this standard is integral to the SE determination, then conformance would need to be established before the 510(k) is submitted.

4. **What advantage, if any, is there for a firm to use a third party to assess conformance with design controls or recognized standards? If a firm does use a third party for the assessment, should this information be included in the 510(k) submission?**

Many device manufacturers employ third parties in assessing conformance with design controls or standards as a matter of routine practice. Although it is ultimately the submitter's responsibility for assuring conformance when electing to submit a declaration of conformity in a premarket submission, third party involvement may provide the

manufacturer with added confidence when submitting a declaration and provide the Agency with additional assurance of conformance. Involvement by an independent, technically competent third party can only benefit the overall process. In The New 510(k) Paradigm, it is stated that if a manufacturer uses a third party to perform a conformance assessment of design control requirements or standards, this information should be maintained in the firm's device master record (DMR). In Attachment 4 of the document, however, it is stated that the declaration to conformity to a recognized standard should include the name and address of any test laboratory or certification body involved in the conformance assessment as well as a reference to the accreditation of the third party. To clarify this issue, the Agency recommends that 510(k) submitters follow Attachment 2 and 4, when preparing declarations of conformity to design controls and standards, respectively. Thus, declarations of conformity to standards should include the name, address, and accreditation of all third parties involved in the conformance assessment. Declarations of conformity to design controls, however, would not need to include this information.

5. **What happens if the Agency determines that a Special or an Abbreviated 510(k) can not be reviewed as such? Is the submission rejected? Is the review clock reset?**

If the Agency determines that a Special or an Abbreviated 510(k) is not eligible for review as submitted, the reviewer will notify the firm of this decision and offer the option of having the document converted to a Traditional 510(k) or withdrawing it for future submission. If the 510(k) is converted, the original receipt date remains as the start of the review period. Manufacturers should be aware that, in most cases, additional information will be necessary for converted documents.

Questions Related to Special 510(k)s

1. **For Special 510(k)s, Attachment 2 of the guidance document states that the manufacturer's declaration of conformity should include a statement that "all verification and validation activities were performed.…" Since some of these activities are not usually performed until just prior to marketing, what activities should be performed prior to submission of the Special 510(k)?**

This statement in the declaration of conformity is intended to capture the manufacturer's compliance with those verification and validation activities that are related to the design modification(s). Therefore, prior to submission of a Special 510(k), FDA would expect that the verification and validation activities, as identified by the risk analysis to ensure that the modified device is as safe and effective as the predicate device, would be completed and would demonstrate that the predetermined acceptance criteria had been met. In accordance with the Quality System Regulation, however, all process validation must be completed and appropriately documented before commercialization of the device.

2. **If a firm obtains clearance for a Special 510(k), will the firm necessarily be inspected to verify conformance with design controls?**

No. The Office of Compliance is developing an audit program to help determine if firms that submitted Special 510(k)s were in fact in conformance with design control requirements. This does not mean, however, that all firms that submit Special 510(k)s will be audited. Under the pilot program, a limited number of cleared submissions will be identified for verification of conformance with design controls by inspection. If a firm is to be inspected, the Agency will notify the firm ahead of time and follow established GMP inspection procedures.

Having stated the above, manufacturers are reminded that routine GMP inspections for Class II and III devices are required by the statute. Thus, submitters of 510(k)s for such devices are subject to inspection whether the premarket notification is submitted for review as an Abbreviated, a Special, or a Traditional 510(k).

3. **For Special 510(k)s that were submitted but later determined to be ineligible for review as such, what were the most common reasons for this determination?**

The most frequently observed problem with Special 510(k)s has been related to the design control information that was submitted in support of the device modification. Several submissions did not include a complete declaration of conformity to design controls. Other submissions included a statement indicating that the firm would comply with the design control requirements rather than a statement that the firm is in conformance. In a few 510(k)s, it was determined that the firm did not perform a complete risk analysis for the device modification.

Finally, one of the other problems observed with the Special 510(k)s that have been submitted for review has been related to the device modification that is the subject of the submission. As discussed in the Guidance, changes to the intended use and fundamental scientific technology should be submitted as Abbreviated or Traditional 510(k)s rather than as Special 510(k)s. Several of the Special 510(k)s that were submitted included a change to either the intended use or to the fundamental scientific technology.

Question Related to Abbreviated 510(k)s

1. **How many standards has FDA recognized? Where can the current list of recognized standards be found?**

FDA has recognized approximately 400 standards to which 510(k) submitters can declare conformity. The list of these standards can be found at on the World Wide Web at: www.fda.gov/cdrh/modact/recstand.html. The Agency will update this list on a periodic basis.

2. **Is the 30 day review clock for Special 510(k)s also applicable to Abbreviated 510(k)s?**

No. While the Agency expects that declarations of conformity to standards will reduce the review time for Abbreviated 510(k)s compared to Traditional 510(k)s, FDA did not establish a 30 day review clock for Abbreviated 510(k)s.

3. **Could a submitter be held liable if a declaration of conformity to a standard is based on information that turns out to be false? What if the information was provided to the submitter by a third party? What are the consequences of submitting a false declaration of conformity?**

Yes. Submitting a false declaration of conformity to a standard is specifically identified as a prohibited act in section 301(x) of the act. If it is determined that the information underlying the declaration of conformity is false or misleading in any material respect, the submitter of the declaration could be held liable. This is true whether the information was generated by the submitter or by a third party (e.g., a testing facility). Therefore, it is important that a person declaring conformity to a standard carefully review the information forming the basis for the declaration before it is submitted to the Agency.

Having stated the above, the Agency does wish to distinguish a "false" or "misleading" declaration of conformity from a declaration of conformity in which FDA disagrees with the adequacy of the supporting data. The Agency acknowledges that a manufacturer may make a good faith effort to conform with a standard and yet FDA may disagree with the basis upon which the declaration was made. Under such circumstances, the Agency will make every effort to resolve the issue with the submitter.

4. **During the review of a 510(k), does FDA anticipate that it will routinely ask for the data or information supporting a declaration of conformity to a standard?**

Section 514 of the act authorizes the Agency to request, at any time, data or information relied upon for the declaration of conformity. FDA does not, however, expect that this would routinely occur, but rather only on a case-by-case basis if a serious concern arises during the review of the submission. The concurrence of senior management would be needed before such a request would be made.

5. How long should the records supporting a declaration of conformity to a standard be maintained?

Section 514 of the act requires persons declaring conformity to a standard to maintain data and information demonstrating conformity of the device to the standard for two years after the date of the substantial equivalency determination or for a period equal to the expected design life of the device, whichever is longer.

For additional questions and answers on the use of recognized standards in premarket submissions, please see "Frequently Asked Questions on Recognition of Consensus Standards" which can be found at: www.fda.gov/cdrh/modact/faqost.html.

Special 510(k): Device Modification

[Date of Submission] *[Company Letterhead]*

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Reference : *[List Original 510 (k) number, trade name and date of concurrence]*

Dear Madam/Sir:

The *[Company Name]* hereby submits this **Special 510(k): Device Modification** to request a modification for our Angiographic Catheters. The modification is to change the hub/shaft bonding process and add a 7F catheter line. We believe these modifications are eligible for the Special 510 (k) process since they have the same fundamental scientific technology and intended use as the predicate device.

We consider our intent to market this device as confidential commercial information and requests that it be treated as such by FDA. We have taken precautions to protect the confidentiality of the intend to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at *[Phone Number]*.

Sincerely,

[Name of Submitter]
[Title]

Special 510 (k) - Angiographic Catheter Modification

Table of Contents

Attachments

CDRH SUBMISSION COVER SHEET	
Date of Submission:	FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modules submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trails ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☐ Original submission ☐ Traditional ☐ Special ☐ Abbreviated ☐ Additional information ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B Applicant or Sponsor

Company / Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code): ( )
Street address:		FAX number (include area code): ( )
City:	State/Province:	Country:
Contact name:		
Contact title:		Contact e-mail address:

Section C Submission correspondent (if different from above)

Company/Institution name:		Establishment registration number:
Division name (if applicable):		Phone number (include area code): ( )
Street address:		FAX number (include area code): ( )
City:	State/Province:	Country:
Contact name:		
Contact title:		Contact e-mail address:

Section D1 Reason for Submission - PMA, PDP, or HDE

- ❑ New device
- ❑ Withdrawal
- ❑ Additional or expanded indications
- ❑ Licensing agreement

- ❑ Change in design, component, or specifications:
  - ❑ Software
  - ❑ Color Additive
  - ❑ Material
  - ❑ Specifications
  - ❑ Other (specify below)

- ❑ Location change:
  - ❑ Manufacturer
  - ❑ Sterilizer
  - ❑ Packager
  - ❑ Distributor

- ❑ Process Change:
  - ❑ Manufacturing
  - ❑ Sterilization
  - ❑ Packaging
  - ❑ Other (specify below)

- ❑ Labeling change:
  - ❑ Indications
  - ❑ Instructions
  - ❑ Performance characteristics
  - ❑ Shelf Life
  - ❑ Trade Name
  - ❑ Other (specify below)

Report submissions:

- ❑ Annual or periodic
- ❑ Post-approval study
- ❑ Adverse reaction
- ❑ Device defect
- ❑ Amendment

- ❑ Response to FDA correspondence:
  - ❑ Request for applicant hold
  - ❑ Request for removal of applicant hold
  - ❑ Request for extension
  - ❑ Request to remove or add manufacturing site

- ❑ Change in ownership
- ❑ Change in correspondent

- ❑ Other reason (specify):

Section D2 Reason for Submission - IDE

- ❑ New device
- ❑ Addition of institution
- ❑ Expansion/extension of study
- ❑ IRB certification
- ❑ Request hearing
- ❑ Request waiver
- ❑ Termination of Study
- ❑ Withdrawal of application

- ❑ Unanticipated adverse effect
- ❑ Notification of emergency use
- ❑ Compassionate use request

- ❑ Treatment IDE
- ❑ Continuing availability request

- ❑ Other reason (specify):

- ❑ Change in:
  - ❑ Correspondent
  - ❑ Design
  - ❑ Informed Consent
  - ❑ Manufacturer
  - ❑ Manufacturing process
  - ❑ Protocol - feasibility
  - ❑ Protocol - other
  - ❑ Sponsor

- ❑ Report Submission:
  - ❑ Current investigator
  - ❑ Annual progress
  - ❑ Site waiver limit reached
  - ❑ Final

- ❑ Response to FDA letter concerning:
  - ❑ Conditional approval
  - ❑ Deemed approved
  - ❑ Deficient final report
  - ❑ Deficient progress report
  - ❑ Deficient investigator report
  - ❑ Disapproval
  - ❑ Request extension of time to respond to FDA
  - ❑ Request meeting

Section D3 Reason for Submission - 510(k)

- ❑ New device
- ❑ Addition or expanded indications

- ❑ other reason (specify):

- ❑ Change in technology
- ❑ Change in design

- ❑ Change in materials
- ❑ Change in manufacturing process

Section E Additional Information on 510(k) Submissions				
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data:
1	2	3	4	❑ 510 (k) summary attached ❑ 510 (k) statement
5	6	7	8	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F Product Information - Applicable to All Applications

Common or usual or classification name:

Trade or proprietary or model name	Model number
1	
2	
3	
4	
5	

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission : ☐ Laboratory testing ☐ Animal trials ☐ Human trials

Section G Product Classification - Applicable to All Applications

Product code:	C.F.R. section	Device class: ☐ Class I ☐ Class II ☐ Class III ☐ Unclassified

Classification panel:

Indications (From labeling):

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing/ Packaging / Sterilization Sites

❑ Original ❑ Add ❑ Delete	FDA establishment registration number:	❑ Manufacturer ❑ Contract sterilizer ❑ Contract manufacturer ❑ Repackager/relabeler	
Company/institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		Fax number (include area code):	
City:	State/Province:	Country:	ZIP/Postal Code:
Contact Name:			
Contact Title:		Contact e-mail address:	
❑ Original ❑ Add ❑ Delete	FDA establishment registration number:	❑ Manufacturer ❑ Contract sterilizer ❑ Contract manufacturer ❑ Repackager/ relabeler	
Company/institution name:		Establishment registration number:	
Division name (if applicable): N/A		Phone number (include area code): ( )	
Street address:		Fax number (include area code): ( )	
City:	State/Province:	Country:	ZIP/Postal Code:
Contact Name:			
Contact Title:		Contact e-mail address:	

Device Name

The device trade names and common/classifications names are:

Device Trade Name	Common/Classification Name
[Trade Name]	Angiographic Catheter

Address and Registration #

The address and registration number of the manufacturer and sterilization sites for both catheters are:

Manufacturer	Sterilization Site
[Company Name] *[Company Address]* FDA Registration #: *[Number]*	*[Company Name]* *[Company Address]* FDA Registration #: *[Number]*

Device Class

Angiographic catheters have been classified as Class II, 74 HBY. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Angiographic catheters.

Predicate Device Information

The predicate device is the *[Trade Name]* Angiographic Catheter, *[510 (k) Number, concurrence date]*.

Labeling and Intended Use

Draft labels and Instructions for Use can be found in Attachment 1.
[Make statement that no changes to the labels or Intructions for Use have occurred or identify what changes have been made].

Intended Use

The *[Trade Name]* Angiographic Catheters intended use are for the delivery of diagnostic agents in the intravascular system. This is the **same intended use** as previously cleared for the *[Trade Name]* Angiographic Catheter , *[510 (k) Number]*.

The Indications for Use statement can be found in Attachment 2.

Continued on next page

Device Description and Comparison

The device description of the *[Trade Name]* Angiographic Catheters is as follows.

- 4 - 7 French
- 50 - 150 cm length
- Polyurethane hub insert molded to a braided nylon shaft.
- Maximum burst pressure of 1200 psi
- .038" maximum guidewire diameter

The only modifications that were made are:

1. Change the hub/shaft bonding process from an adhesive bond to insert molding.
2. Expand the product line from 4, 5, & 6F to add a 7F version catheter.

*[**Note:** Before and after statements are recommended by FDA to clarify the modifications being made].*

Substantial Equivalence

The modified angiographic catheters have the following similarities to those which previously received 510(k) concurrence:

- have the same indicated use,
- use the same operating principle,
- incorporate the same basic catheter design,
- incorporate the same materials,
- have the same shelf life, and
- are packaged and sterilized using the same materials and processes.

*[**Note:** Listing the similarities is optional, however, it may reduce the need for the reviewer to verify this information in the previous submission].*

In summary, the *[Trade Name]* Angiographic catheters described in this submission are, in our opinion, substantially equivalent to the predicate device.

Continued on Next Page

Summary of Design Control Activities

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA).[2] The design verification tests that were performed as a result of this risk analysis assessment are listed in Table 1 below.

TABLE 1 - Verification Tests

Modification	Test Performed	Acceptance Criteria
Change Hub/Shaft Bond Process	• hub/shaft pull strength test	• 1.0 lbs
Addition of 7F Product Line	• dimensional inspection • hydrostatic pressure test • flow rate test	• per drawing • 1200 psi • >5ml/sec

The test methods used are the same as those submitted in the original submission.

A declaration of conformity with design controls is included in Attachment 3.

510(k) Statement

A 510(k) Statement for the *[Trade Name]* Angiographic Catheters is included in Attachment 4.

*[**Note:** This can be replaced by a 510 (k) summary].*

Truthful and Accuracy Certification

A certification of the truthfulness and accuracy of the *[Trade Name]* Angiographic Catheters described in this submission is provided in Attachment 5.

End

[2] Manufacturer should list which risk analysis method was used.

Attachment 1

Labels and IFU's

Attachment 2

Indications for Use Statement

510(k) Number (if known)

Device Name *[Trade Name]* Angiographic Catheter

Indications for Use The *[Trade Name]* Angiographic Catheter intended use is for the delivery of diagnostic agents in the intravascular system.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Attachment 3

Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, 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.

_____ _____

[Name] *[Date]*
[Title]
[Company]

Manufacturing Facility

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.

_____ _____

[Name] *[Date]*
[Title]
[Company]

[NOTE: The above two statements should be signed by the designated individual (s) responsible for those activities].

Attachment 4

510 (k) Statement

Statement

I certify that, in my capacity as (the position held in company by the person required to submit the premarket notification, preferably the official correspondent), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

[Signature of certifier]

[Typed Name]

[Dated]

Attachment 5

Truthful and Accuracy Statement

Pursuant to 21 CFR 807.87(j), I *[Name]*, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as *[The position held in Company]* of *[Company Name]*, and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

_____

[Signature]

_____

[Typed Name]

_____

[Dated]