Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices

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For questions regarding this document, contact:

- Peter L. Hudson, Ph.D., Plastic and Reconstructive Surgery Branch, at 240-276-3600, or by e-mail at peter.hudson@fda.hhs.gov.
- Doyle Gantt, Peripheral Vascular Devices Branch, at 240-276-4000, or by e-mail at a.gantt@fda.hhs.gov.
- Colin M. Pollard, Obstetrics and Gynecology Devices Branch, at 240-276-4155 or by e-mail at colin.pollard@fda.hhs.gov.

This document will supersede "Guidance for Neurological Embolization Devices" dated November 1, 2000" and the draft guidance "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices" dated February 25, 2004.

C·D·R·H
Center for Devices and Radiological Health

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

Division of General, Restorative, and Neurological Devices
Plastic and Reconstructive Surgery Devices Branch

Division of Cardiovascular Devices
Peripheral Vascular Devices Branch

Division of Reproductive, Abdominal, and Radiological Devices
Obstetrics and Gynecology Devices Branch

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to **Docket No. 2003D-0568**. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices

This guidance document represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance document. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance document.

1. Introduction

This guidance document was developed as a special controls guidance document to support the reclassification of the vascular embolization device and the neurovascular embolization device into class II. The vascular embolization device is intended to control hemorrhaging due to aneurysms, certain types of tumors (e.g., nephroma, hepatoma, and uterine fibroids), and arteriovenous malformations. The neurovascular embolization device is intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. FDA believes that the risks to health associated with the intended uses of the vascular embolization and the neurovascular embolization devices are the same. Therefore, FDA believes that a single guidance document can serve as the special control for both device types.

This guidance document is issued in conjunction with a Federal Register notice announcing the reclassification of the vascular embolization device and the neurovascular embolization device types. Following the effective date of the final rule reclassifying these devices, any firm submitting a 510(k) for a vascular embolization device or a neurovascular embolization device will need to address the issues covered in the special control guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant

statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the vascular embolization device and the neurovascular embolization device. Thus, a manufacturer who intends to market a device of one of these generic types should (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with these devices identified in this guidance document, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification regulations and product codes for these devices (Refer to Section 4 – **Scope)**. In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these devices and lead to a timely 510(k) review and clearance. This document supplements other FDA documents regarding the content requirements of a 510(k) submission. You should also refer to CDRH's **Device Advice** http://www.fda.gov/cdrh/devadvice/ and 21 CFR § 807.87.

As described in the guidance document entitled, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**, http://www.fda.gov/cdrh/ode/parad510.html, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a class II special controls guidance document has been issued. Manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Please refer to **Section 11** for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

We recommend that the summary report contain:

Description of the device and its intended use

We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Please refer to **Section 5**. **Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[1]

Description of device design requirements

We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method

We recommend that you identify the Risk Analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design and the results of this analysis. (Please refer to **Section 6**. **Risks to Health** for the risks to health generally associated with the use of this device that FDA has identified.)

[1] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the risks identified in this class II special controls guidance document, as well as any additional risks identified in your risk analysis.

Description of the performance aspects

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 7-10** of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[2] (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

Reliance on standards

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that testing will be conducted and meet specified acceptance criteria before the product is marketed; or
- declaration of conformity to the standard.[3]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the Act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR § 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that

[2] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[3] See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), http://www.fda.gov/cdrh/ode/reqrecstand.html.

provides all of the information and data required under 21 CFR § 807.87 and described in this guidance document. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a 510(k) submission for a vascular embolization device or a neurovascular embolization device. The recommendations made in this guidance document apply to both, unless vascular or neurovascular is specified.

4. Scope

The scope of this document is limited to the following two device types:

Device Type	**Classification Regulation** (21 CFR)	**Product Code**	**Examples**
Vascular embolization device	§ 870.3300	KRD (device, embolization, arterial)	• embolization coils • detachable balloons • polyvinyl alcohol particles • nonresorbable particles
		NAJ (agents, embolic, for treatment of uterine fibroids)	• nonresorbable particles
Neurovascular embolization device	§ 882.5950	HCG (device, artificial embolization)	• embolization coils • polyvinyl alcohol particles • nonresorbable particles
		MZQ (balloon, detachable, for neurovascular occlusion)	• detachable balloons

In the companion final rule, FDA is revising the names and identifications of these embolization device types, §§ 870.3300 and 882.5950, as described below.

§ 870.3300 – Vascular embolization device.

(a) *Identification*. A vascular embolization device is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors (e.g., nephroma, hepatoma, uterine fibroids), and arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in neurovascular applications are also not included in this classification, see 21 CFR 882.5950.

(b) *Classification*. Class II (special controls). The special control for the device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices."

§ 882.5950 – Neurovascular embolization device.

(a) *Identification*. A neurovascular embolization device is an intravascular implant intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in other vascular applications are also not included in this classification, see 21 CFR 870.3300.

(b) *Classification*. Class II (special controls). The special control for the device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices."

Cyanoacrylates and other embolic devices (product code NPE), which act by polymerization or precipitation, continue to be regulated as postamendments class III devices and require premarket approval (PMA) applications.

5. Device Description

We recommend that you identify your device by regulation number and product code and include the following information:

- identity of the reagents and raw materials (i.e., reagent source, purity, Certificates of Analyses (CoA), or Material Safety Data Sheets (MSDS)) used in the construction of the device and any voluntary material conformity standards
- identity and quantity of any manufacturing reagent (e.g., organic solvents, heavy metals, cross-linking reagents remaining in the device) that is potentially toxic
- a description of the components of the device and its assembly
- a description of any accessories and ancillary devices used with the device (e.g., delivery catheters)
- the range of dimensions, shapes, and device designs
- engineering drawings
- a description of the principle of operation (i.e., method of deployment and embolization)
- a description of how the device is provided (e.g., sterile, assembled, single use).

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the devices addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. We recommend that you also conduct a risk analysis, prior to submitting your 510(k), to identify any other risks specific to your device. For example, a device with gynecological indications may present additional risks, such as damage to the uterine wall, diffuse uterine necrosis, primary ovarian failure, reproductive toxicity, or carcinogenicity, as well as other risks related to the chemistry, toxicology, and healing response in the uterine environment. The 510(k) should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, then you should provide sufficient detail to support the approach you have used to address that risk.

Identified Risk	**Recommended Mitigation Measures**
Blood vessel perforation or rupture	Section 7: Preclinical Testing Section 9: Animal Testing Section 10: Clinical Testing Section 11: Labeling
Unintended thrombosis	Section 7: Preclinical Testing Section 9: Animal Testing Section 10: Clinical Testing Section 11: Labeling
Adverse tissue reaction	Section 7: Preclinical Testing Section 9: Animal Testing Section 10: Clinical Testing
Infection	Section 8: Sterility
Hematoma formation	Section 7: Preclinical Testing Section 9: Animal Testing Section 10: Clinical Testing Section 11: Labeling

7. Preclinical Testing

We recommend that you conduct the preclinical testing below to establish the performance characteristics of the device.

Polyvinyl Alcohol (PVA) Particle Testing

We recommend that you provide the following for PVA particles:

- chemical analysis of the final sterilized device, including identification and quantification of any processing additives, contaminants, etc.
- if applicable, an explanation of how formaldehyde and/or other processing materials are removed from the particles and data evaluating the removal process

- particle size ranges
- assessment of particle size compatibility with the recommended delivery catheter(s)
- evaluation of the uniform dispersion and suspension of particles within the catheter when mixed with the recommended contrast agent(s) or other interactive material(s) according to the labeled instructions.

Detachable Balloon Testing

We recommend that you provide the following for detachable balloons:

- the inflation/deflation rates for each balloon size
- the pressure(s) and volume(s) required to rupture the balloon(s) and the release specification for the maximum inflation pressure and volume
- a plot of volume versus inflation pressure
- the force needed to detach the balloon
- the balloon permeability with recommended contrast
- the reliability of the detachment mechanism.

Embolization Coil Testing

We recommend that you provide the following for embolization coils:

- the coil strength (i.e., the force required to deform the coil shape – primary and secondary diameters, as well as coil tensile strength, torsional resistance and fatigue)
- the ease of delivery, as measured by friction when advancing and/or retracting the coil through a recommended catheter positioned in a simulated tortuosity
- for coils with fibers, a description of the fiber attachment mechanism and pull-out force
- a description of the detachment mechanism and data on the detachment time
- the reliability of the detachment mechanism.

Delivery Catheter Testing

If your 510(k) includes a new delivery catheter, we recommend that you provide the following information for that catheter:

- length and outside diameter of the catheter
- tensile strength
- catheter burst/leakage pressure
- flexibility
- a plot comparing the flow rate of fluid through the catheter versus the applied internal pressure
- hub attachment strength
- kink resistance

- radiopacity
- coefficient of friction of the external surface of the catheter
- if the catheter is coated, a description of the coating material, coating process and data supporting the purpose of the coating
- corrosion resistance.

For additional details regarding catheter information and testing, FDA suggests that you refer to **International Standard ISO-10555, Sterile, Single-Use Intravascular Catheters**.

Shelf Life

We recommend that you conduct both preclinical and packaging testing to establish the shelf life (i.e., expiration date) of the device as a part of the validation activities required by the Quality Systems Requirements (21 CFR Part 820). Accelerated test results should be supported by validated test information, and, depending on the device component, should also be supported by real time test data. For mechanical testing, you should conduct both preclinical and packaging testing on representative aged samples. For packaging testing, we recommend that you conduct testing on the final finished package measuring initial integrity and the maintenance of integrity. We recommend that you use test methods that are either validated or standardized. The documentation from these validation activities must be maintained in the Design History File for the device (21 CFR § 820.30).

Biocompatibility

FDA recommends that you select tests appropriate for implant devices with tissue/bone and blood contact as described in the FDA-modified **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**, http://www.fda.gov/cdrh/g951.html.

We recommend that you perform carcinogenicity studies with devices in which a positive genotoxicity test result was obtained. We recommend that you take into consideration identities of the chemical components and available information regarding their toxicity in your evaluations of potential carcinogenicity.

For neurovascular embolization devices, because ethylene oxide (EO) may cause neurotoxicity, in addition to measuring the EO residue levels, we recommend that you provide biocompatibility information on the finished EO-sterilized device using intracranial implantation to assess any adverse tissue response, or cite other equivalent legally marketed predicate products that undergo EtO sterilization. You should demonstrate that the level of sterilant residues remaining in the device do not raise concerns over the safe use of the product.

Pyrogenicity

Because of the potential for contact with the intrathecal space, the amount of endotoxin in the final, sterilized, neurovascular embolization device should be less than 0.06 Endotoxin Unit (EU)/mL and in the vascular embolization devices, less than 0.5 EU. These recommendations are described in the "Guideline on validation of the Limulus Amebocyte Lysate test as an end-product endotoxin test for human and animal parenteral drugs, biological products, and medical devices," December 1987, http://www.fda.gov/cder/guidance/old005fn.pdf.

8. Sterility

FDA recommends that you provide sterilization information as described in the **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/361.html. The device should be sterile with a sterility assurance level (SAL) of 1×10^{-6}. Refer to the Biocompatibility section above for testing related to EO-sterilized devices.

9. Animal Testing

We generally recommend that you conduct a pre-clinical animal model evaluation to evaluate these devices to show that you have adequately addressed the risks identified in this guidance document. Animal testing should be considered in the absence of an appropriate bench model. For new device design features affecting the embolic agent itself (e.g., coatings to coils, coil structural design, coil materials, particle materials, particle shape, sizes), the mechanism of detachment, or the catheter itself, we recommend that the animal study evaluate:

- ease of delivery (friction and tortuosity)
- acute complications (e.g., rupture or puncture of the blood vessels)
- recanalization of the vessels/durability of occlusion
- local and systemic foreign body reactions
- device migration
- embolization effectiveness.

Because changes in embolization agent design and materials of construction may influence the healing process of the embolization site, we recommend that you perform follow-up evaluations with appropriate frequency and after sufficient time has passed to evaluate acute as well as chronic toxicity. Evaluating chronic toxicity helps ensure that the response to the embolic agent has stabilized or is in the process of resolution. We also recommend that you provide an explanation of how the animal model relates to the human condition through any pertinent literature references and/or supporting testing.

10. Clinical Testing

In accordance with the least burdensome provisions of the Act, FDA will rely upon well-designed bench and/or animal testing rather than requiring clinical studies for new devices unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While, in general, clinical studies will not be needed for most vascular or neurovascular embolization devices, FDA may recommend that you collect clinical data for a vascular or neurovascular

embolization device with:

- designs or material formulations (e.g., coatings to coils, coil structural design, coil materials, particle materials, particle shape, sizes, mechanism of detachment, novel catheter design) dissimilar from designs or material formulations used in legally marketed devices of the same type
- new technology (i.e., technology different from that used in legally marketed devices of the same type)
- indications for use dissimilar from devices of the same type.

Vascular and neurovascular embolization devices are classified as different generic types of devices, thus FDA does not consider them to be "of the same type" in the criteria described above.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. The review branches identified on the cover of this guidance document are available to discuss any clinical testing with you before you initiate your studies.

If a clinical study is needed to demonstrate substantial equivalence (i.e., conducted prior to obtaining 510(k) clearance of the device), the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812. FDA believes that the vascular and neurovascular embolization devices addressed by this guidance document are significant risk devices as defined in 21 CFR § 812.3(m).[4] In addition to the requirement of having an FDA-approved IDE, sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

After FDA determines that the device is substantially equivalent, clinical studies conducted in accordance with the cleared indications, including clinical design validation studies conducted in accordance with the quality systems regulation, are exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance with 21 CFR Part 56 and 21 CFR Part 50.

We recommend that you consider the information below specific to embolization clinical studies.

Endpoints

We recommend that the study protocol include clearly defined primary and secondary endpoints and specific success/fail criteria for the study. We recommend that you define and report all adverse events.

We recommend that effectiveness endpoints include the reduction in size of the vascular lesion, percentage occlusion of an aneurysm, or the occlusion of a parent vessel as measured by angiography. We also recommend that you consider other endpoints, such as the recanalization rate of the embolized vascular lesion and/or the determination of the clinical benefit. For example, for devices used for presurgical embolization, a reduction in surgical time and blood loss may be appropriate endpoints.

For neurovascular embolization devices, we recommend that the safety evaluation include:

[4] Refer to Blue Book Memorandum entitled "SIGNIFICANT RISK AND NONSIGNIFICANT RISK MEDICAL DEVICE STUDIES" at http://www.fda.gov/cdrh/d861.html.

- the incidence of new neurological deficits (transient and permanent)
- neurological outcome assessment
- the rate of neurological and non-neurological complications
- distal migration of particular material.

We recommend that you identify the measurement tools used to assess patient neurological endpoints. We recommend that you evaluate all patients, at a minimum, pre-embolization, immediately post-embolization, and at a follow-up examination using a standard neurological examination that tests:

- cranial nerves
- sensory function
- motor function and reflexes
- gait and coordination
- mentation.

We recommend that you provide a copy of the neurological examination as a case report form on which the clinician will record results. Other means of measuring endpoints may include:

- functional outcome scales
- patient self-reports
- clinician or surgeon self-reports (World Federation of Neurosurgeons grade (WFNS), Glasgow Outcome Scale (GOS), Glasgow Coma Scale (GCS), NIH Stroke Scale, and/or Barthel Index).

We recommend that the evaluation of endpoints be independent and masked. For any scale used, we recommend that the directions for determining values in the test be part of the case report form and that the scale range be indicated on the case report form where the score will be entered.

Description of Embolization Procedure

We recommend that you provide a full description of the embolization procedure in the protocol, including:

- device/component assembly and preparation
- use of anticoagulation medication (e.g., drug, dose)
- use of antibiotics
- circumstances under which adjunctive embolization devices may be used during the procedure
- whether there is a plan for staged embolization and the features of that plan
- the therapy available in the event of stroke or other complication during the embolization procedure
- the time interval between embolization and definitive resection if embolization is a pre-surgical procedure.

In addition, we recommend that you monitor the neurological function during implantation of neurovascular embolization devices in patients under local anesthesia.

Imaging

Pre-operative imaging procedures are standard of care for patients requiring embolization. In addition to pre-operative evaluation, post-embolization angiography and short-term and long-term follow-up imaging scans may be appropriate when evaluating embolization agents with novel design features. We recommend that you describe the methods used to measure the lesion (e.g., angiography, MRI, MRA, CT), as well as the follow-up intervals. Because the vascular disorder and device use may determine which imaging tools are used and the length and interval of follow-up, we recommend that you provide the rationale for these protocol elements along with any supporting literature/studies.

Patient Follow-up

We recommend that you specify how often patients should be evaluated during follow-up.

11. Labeling

The 510(k) should include labeling in sufficient detail to satisfy the requirements of 21 CFR § 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR Part 801.[5]

Prescription Use

As a prescription device, under 21 CFR § 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR § 807.87(e), we expect to see clear and concise instructions that delineate the technological features of the specific device and how the device is to be used on patients. Instructions should encourage appropriate training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

Instructions for Use

We recommend that the instructions for use include:

- the minimum and maximum internal diameter of the embolization delivery catheter
- information on any contrast media and flushing agent used with your device
- for a detachable balloon, the pressure required to rupture the balloon and the specification for the maximum inflation pressure and volume.

[5] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR § 801.109. Labeling recommendations in this guidance document are consistent with the requirements of Part 801.