This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer 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. This guidance will be updated in the next revision to include the standard elements of GGP's.

Coronary and Cerebrovascular Guidewire Guidance
January 1995

Coronary guidewires are pre-amendment class II devices (21 CFR 870.1330) and can only be marketed after receiving a substantial equivalence determination from FDA on a premarket notification (510(k)) submission. *(Cerebrovascular guidewires were not specifically classified; therefore, cerebrovascular guidewires are based upon the coronary guidewire classification.)* This document is intended to outline the types of scientific data considered necessary for submission in an investigational device exemptions (IDE) application, when applicable, and in a 510(k) application.

The following information is considered to be necessary:

1. Intended Use - Clearly specify the intended use(s) of the device. For example:

   a. to facilitate the placement of catheters within the coronary arteries, and/or
   b. to facilitate the placement of catheters within the cerebrovasculature for imaging the vasculature or for the delivery of approved embolization agents such as coils, PVA, or silicone spheres.

2. Characterization - Provide a detailed engineering drawing(s) with a detailed discussion of device design/construction including identification of:

   a. all materials (i.e., core wire, adhesives, solders, coatings, etc.),
   b. all wire diameters and lengths,
   c. all safety wires and ribbons,
   d. all joints (adhesive and solder/braze),
   e. any radiopaque markers, and
   f. the configuration, length, and material of the distal tip.

3. Performance Data - Please provide the test protocols and all results (not just a summary), with comparisons to predicate devices with the same intended uses, for the following specified tests (testing should be performed on final, sterilized devices). All in-vitro test specifications, if noted, must be justified in relation to expected clinical conditions for the device. Adequate justification must be provided for any tests not conducted.

   a. Tensile Strength - Verify that the device and all its joints (adhesive/solder/braze) are sufficiently strong to withstand normal tensile loading for the intended use. Testing should be conducted on at least ten (10) of each of the smallest and largest diameter wires. The test protocol should specify the pull rate used in each test.

   b. Torque Strength - Verify that the device and all its joints (adhesive/solder/braze) are sufficiently strong to withstand normal rotational loading for the intended use. Testing should be conducted in a simulated, tortuous, coronary anatomy (over-the-arch test), with the distal tip being fixed, on at least ten (10) of each of the smallest and largest diameter wires. Results should be presented as the number of turns-to-failure.

   c. Torqueability - Demonstrate the correlation between rotation of the proximal end and the corresponding rotation of the distal end of the wire. Testing should be conducted in a simulated, tortuous, coronary anatomy (and cerebral anatomy, if applicable) on at least five (5) of each of the smallest and largest diameter wires. Results should compare the proximal rotational input and the resulting distal rotation at 90° intervals.

   d. Tip Flexibility - Demonstrate the force required to deflect the distal tip of five (5) of each of the smallest and largest diameter wires to 45° and 90° when the wire is fixed at 5, 10, and 20 mm from the distal tip and compare to results of similar testing of the predicate device(s). These results should also be compared to the intended use environment.

e. Coating Adherence/Integrity - Verify that the coating material, if present, will not flake, peel, or rub off during simulated clinical use. Conduct testing on at least 10 devices.

f. Biocompatibility - Verify that all materials (including adhesives and solders) are safe for the intended use. Follow the recommendations of the Tripartite Biocompatibility Guidance for Medical Devices and provide a detailed scientific justification for any test(s) not performed. All test protocols and results should be submitted to FDA.

g. Catheter Compatibility - Show that the guidewire is compatible with the catheters to be used during the applicable procedure (whether coronary and/or neuroradiological use). Identify any catheters that are not suitable for use with the guidewire.

4. Bench Testing - **For Neurovascular Use** - Sponsor must replicate the tortuosity, dimensions, and other characteristics of the vasculature and should demonstrate a comparable resistance to the passage of the guidewire during its insertion and removal.

5. Animal Testing and Human Clinical Trials - (*see attached for details*)

CORONARY AND CEREBROVASCULAR GUIDEWIRE GUIDANCE

Testing Requirements for Devices Smaller Than 0.014" Diameter

January 1995

FDA has decided that clinical trials may not be required for guidewires less than 0.014" in diameter. A well designed, controlled in vivo animal study can offer a more in depth and thorough evaluation of the safety and effectiveness of these devices. Below is an outline of the testing and data requirements for these studies.

Test Procedure

- A minimum of three (3) animals should be used (a rabbit model is adequate)
- To simulate "worst case" clinical use, in terms of tortuosity and vessel size, testing should be conducted in the cerebral vasculature
- At a minimum, a different guidewire should be used for each animal
- Each device should be introduced into the cerebrovasculature system at least five (5) times
- An appropriate currently marketed guidewire should be used as a control

Results

- Provide a detailed description of the pathological observations (gross and microscopic)
- Give an explanation of any abnormalities
- Identify the number and location of the segments studied
- Record qualitative data such as handling characteristics
- Provide a complete and organized comparison of the proposed wire and the control wire

Atherosclerotic Models

Atherosclerotic models are not required for standard guidewires. However if new technological characteristics are introduced with the proposed guidewire design, such as a new material, tip design, stiffness, atherosclerotic model testing or a clinical trial must be conducted

- Perform the above outlined testing in an atherosclerotic animal model
- Testing should include the smallest and largest diameter wires
- Discuss the potential for vessel wall injury (dissection, perforation, etc.) and thromboembolism with the use of the device
- Provide test results to support claims

OR

- Conduct a clinical trial of the largest and smallest diameter wires, in fifteen patients, at each of two institutions
- The study must be conducted under an IDE approved by both FDA and each institution's IRB, prior to initiating the study

Note: Depending on the results, a clinical trial may be required for guidewires that have undergone animal and/or atherosclerotic model testing