Guidance for Industry and FDA Staff

Coronary and Peripheral Arterial Diagnostic Catheters

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Food and Drug Administration
Center for Devices and Radiological Health

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Division of Cardiovascular Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Coronary and Peripheral Arterial Diagnostic Catheters

This guidance 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. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This guidance document provides information that you should consider when preparing premarket submissions for coronary or peripheral arterial diagnostic catheters. Some of these catheters are designed to provide cross-sectional imaging of the arterial lumen and wall, similar to intravascular ultrasound but with improved resolution. Others are designed to evaluate various properties of the artery wall and/or atherosclerotic plaque, for example, local variations in artery wall temperature, the composition of the artery wall (i.e., tissue type and/or chemical composition), and local arterial wall compliance.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances 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 guidances 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 should 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 comply with 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

Regulatory Pathway

The regulatory pathway, i.e., premarket notification submission (510(k)), *de novo* classification, or premarket approval application (PMA), for a coronary or peripheral arterial diagnostic catheter depends on the identification of an appropriate predicate device, the technology of the device, and its indications for use.

In general, ODE will attempt to review these catheters as class II devices under 21 CFR 870.1200 Diagnostic Intravascular Catheters.[1] FDA believes it may be difficult to demonstrate substantial equivalence for arterial catheters with certain diagnostic indications, e.g., identify regions of plaque at risk of rupture. If we are unable to make a substantial equivalence determination from the descriptive characteristics, we will first consider whether *de novo* classification can provide the proper degree of regulatory control. If so, we will communicate this in the not substantially equivalent letter to the submitter, which begins the *de novo* process.[2]

Whether *de novo* classification is appropriate depends, in part, on the risk profile of your device. FDA will review your risk analysis, if you include one in your 510(k) to aid in our evaluation. Please see the section entitled **Evaluation of Safety** for our recommendations about the factors you should address in a risk analysis for these devices.

If we are unable to find a device substantially equivalent, and *de novo* classification is not appropriate, we believe a premarket approval application may be the proper regulatory pathway.[3]

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[1] See "How to Prepare a 510(k) Submission**"** at http://www.fda.gov/cdrh/devadvice/314.html.

[2] For information about the *de novo* process, please see "New Section 513(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff" at http://www.fda.gov/cdrh/modact/classiii.html.

[3] See "Premarket Approval" at http://www.fda.gov/cdrh/devadvice/pma/ and **Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff**, http://www.fda.gov/cdrh/comp/guidance/1140.pdf.

Regardless of regulatory pathway, we recommend that you conduct a thorough evaluation of device safety and effectiveness.

Evaluation of Safety

We recommend that you begin by comparing the descriptive characteristics of your catheter to legally-marketed devices with the same intended uses. We recommend that you compare the following:

- dimensions
- materials
- design
- mechanical properties
- thermal properties.

If the descriptive characteristics of your device are equivalent to those of legally marketed devices, additional testing may not be necessary.

If there are significant differences between your device and the legally marketed predicate devices, then the next step is to consider the risk analysis that you conducted as part of your Quality System procedures. This risk analysis should consider the risks related to:

- device design (e.g., risk of excess device pressure against artery wall);
- procedural method (e.g., risk of plaque dislodgement if the catheter is intended to be "withdrawn" from the artery while making a measurement);
- arterial diameter, structure, or location (e.g., risk when used in carotid artery versus risk when used in femoral artery); and
- anticipated or potential arterial pathology (e.g., risk of plaque rupture and acute thrombosis).

We also recommend that your risk analysis encompass the full, indicated range of clinical use and address the full, indicated range of:

- arterial diameters;
- arterial locations;

- patient populations, with appropriate consideration of all expected degrees and types of arterial disease; and
- extremes of the device's operational parameters, e.g., the maximum inflation time for an occlusion balloon or the maximum distance that a catheter may be withdrawn while making a measurement.

We recommend that you use the assessment of your risk analysis to determine what additional testing is necessary to mitigate any new risks presented by your device. If bench testing is insufficient to fully evaluate the safety of your device, we generally recommend that you conduct animal safety testing. Animal testing enables you to directly evaluate the device safety or to establish safety-related criteria for device design or device use.

For example, our current understanding of non-injurious balloon inflation pressures and the safety of the resulting, transmitted radial pressures may be inadequate when such devices are used in small-diameter coronary arteries; therefore, we recommend that you perform animal testing with these devices to assess their safety when used in small diameter coronary arteries.

If bench and animal testing are insufficient to evaluate the safety of your device, i.e., the assessment of your risk analysis indicates additional testing is necessary, we generally recommend that you conduct a clinical trial. For example, if your device introduces potential risks different from those associated with currently marketed intravascular catheters and if bench testing and animal testing cannot adequately evaluate these new or different potential risks, we recommend that you conduct a clinical trial.

When a device is intended for use in high risk patient populations, we recommend that you conduct clinical testing in a staged fashion, beginning with relatively low-risk patient populations, then moving to higher-risk populations. For example, if a catheter is intended to evaluate the target lesion or the affected artery in patients with acute coronary syndrome (ACS), we recommend that you evaluate device safety first in patients with stable ischemic heart disease, then in non-target-lesion arteries of patients with ACS, then in the target-lesion arteries of patients with ACS.

Similarly, for catheters intended for use in high risk locations, such as atherosclerotic carotid arteries, we recommend that you evaluate device safety first at other, lower risk, arterial locations.

Evaluation of Effectiveness

In order to appropriately assess the potential risks associated with the use of the device, we recommend that you conduct a thorough evaluation of application-specific device effectiveness for any new type of arterial diagnostic catheter.

We recommend that your evaluation of device performance encompass the device's full, indicated range of clinical use.

For catheter types that evaluate standard arterial parameters (e.g., arterial diameter or cross sectional area), one approach that we recommend is to directly compare the performance of the new device to the performance of a currently marketed device such as angiography or intravascular ultrasound catheters. Other approaches may provide an adequate assessment of performance, and we will consider their scientific merits on a case-by-case basis.

For catheters that evaluate novel parameters (e.g., artery wall temperature or artery wall composition), in-vitro and/or in-vivo models may provide the most feasible methods for critical and/or quantitative evaluation of device performance. We recommend that you consider the following two examples when designing such in vitro or in vivo testing:

Catheters Intended to Evaluate Artery Wall Temperature

For catheters that evaluate artery wall temperature, we recommend developing test systems comprising in-vivo or in-vitro arteries "rigged" with artificial "hot spots" for quantitative evaluation of performance.

Catheters Intended to Evaluate Artery Wall or Plaque Composition

For catheters that evaluate artery wall or plaque composition, we recommend developing test systems comprising in-vitro evaluation of freshly-collected arterial specimens and/or heart specimens (explant or autopsy) that can be subsequently evaluated by histopathology for quantitative evaluation of performance.

We recommend that you consider the results from your in-vitro and/or in-vivo model to help determine whether additional animal or clinical studies are necessary to evaluate your device. FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale.

Evaluation of Diagnostic Capabilities

Devices intended to provide diagnostic information, but that provide incorrect or unreliable results, put patients at risk because incorrect information may be used to guide treatment decisions and/or may expose patients to risks associated with unnecessary or inappropriate drug or device therapy. Therefore, in the absence of valid scientific evidence from other sources, FDA has generally recommended that sponsors conduct prospectively defined clinical trials to support the safety and

effectiveness of catheters with diagnostic or predictive indications. The Cardiac Electrophysiology and Monitoring Branch is available to discuss clinical testing and trial design with you before you initiate studies.

If a clinical study is conducted prior to obtaining a 510(k) clearance or PMA approval, the study must be conducted under the Investigational Device Exemptions (IDE) regulation, 21 CFR 812. FDA has determined that the devices addressed by this guidance document are significant risk devices as defined in 21 CFR 812.3(m)(4).[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).

[4] Refer to Blue Book Memorandum entitled "Significant Risk and Nonsignificant Risk Medical Device Studies" at http://www.fda.gov/cdrh/d861.html.