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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2000-P-0924] (formerly Docket No. 2000P-1533)

Cardiovascular Devices; Reclassification of Certain Percutaneous Transluminal Coronary Angioplasty Catheters

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment the recommendation of the Circulatory System Devices Panel (the Panel) to reclassify Percutaneous Transluminal Coronary Angioplasty (PTCA) catheters, other than cutting/scoring PTCA catheters, from class III (premarket approval) to class II (special controls). The Panel made this recommendation after reviewing the reclassification petition submitted by Cook Group Inc. (COOK) and other publicly available information. FDA is also announcing for public comment its tentative findings based on the Panel's recommendation and other publicly available information. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the **Federal Register**. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance document that FDA intends will serve as the special control for this device type, if it is reclassified.

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DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the Federal Register*]

ADDRESSES: You may submit comments, identified by Docket No. FDA-2000-P-0924, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):
Division of Dockets Management (HFA-305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this document. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathryn O’Callaghan or Suzanne Kaiser, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4222.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101-629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976, are generally referred to as postamendments devices, and are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or

II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Section 513(f)(3) of the act, as amended by FDAMA, provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary for the issuance of an order classifying the device in class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(3)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. The Panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (1) a summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Regulatory History of the Device

The PTCA catheter is a postamendments device classified into class III under section 513(f)(1) of the act. Therefore, the device cannot be placed in commercial distribution unless it is subject to an approved premarket approval

application (PMA) under section 515 of the act (21 U.S.C. 360e) or is reclassified.

On September 21, 2000, FDA filed a petition submitted under section 513(f)(3) of the act from COOK requesting reclassification of PTCA catheters from class III into class II (Ref. 1). This reclassification petition did not include cutting or scoring PTCA catheters. In order to reclassify the PTCA catheter into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness of the device for its intended use.

The COOK petition requests reclassification of PTCA catheters from class III to class II when indicated for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. Consistent with the act and the regulation, FDA referred the petition to the Panel for its recommendation on the requested changes in classification. FDA also asked the Panel for its recommendation on the reclassification of PTCA catheters when used for treatment of acute myocardial infarction (MI), treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

III. Device Description

The following device description for the PTCA catheter recommended for reclassification from III to II is based on the Panel's recommendations and the agency's review. The PTCA catheter is a device that operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. A PTCA balloon catheter has a single or double lumen shaft. The catheter features a balloon of appropriate compliance for the clinical application, constructed from a polymer. The balloon is designed to uniformly

expand to a specified diameter and length at a specific pressure as labeled, with well characterized rates of inflation and deflation and a defined burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use. A PTCA catheter is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. A PTCA catheter may also be intended for the treatment of acute myocardial infarction; treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

This notice of panel recommendation does not include cutting/scoring PTCA catheters. A cutting/scoring PTCA catheter is a balloon-tipped catheter with cutting/scoring elements attached, which is used in those circumstances where a high pressure balloon resistant lesion is encountered. A cutting/scoring PTCA catheter is intended for the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion. A cutting/scoring PTCA catheter may also be indicated for use in complex type C lesions or for the treatment of in-stent restenosis.

IV. Recommendation of the Panel

At a public meeting on December 4, 2000, the Panel recommended (seven to one) that PTCA catheters be reclassified from class III to class II, when indicated for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion; or for treatment of acute myocardial infarction. The Panel recommended a guidance document, labeling, and postmarket surveillance as special controls. The Panel stated that the special controls will diminish some of the risks to health associated with

certain PTCA catheters. The guidance document and labeling controls are intended to ensure the appropriate performance and use of the device by physicians. The Panel recommended postmarket surveillance as a special control to confirm that the other special controls being applied to these devices would be sufficient to ensure that there would not be an increase in adverse consequences to patients. In summary, the Panel believed that class II with special controls would provide reasonable assurance of the safety and effectiveness of the device.

V. Risks to Health

After considering the information discussed by the Panel during the December 4, 2000, meeting and other publicly available information (Refs. 2 and 3), FDA believes that certain PTCA catheters should be reclassified into class II because special controls, in addition to general controls, can provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance. Based on the information in the petition, the Panel's deliberations, the published literature, and medical device reports, FDA has identified the following risks to health are associated with the use of PTCA catheters: Adverse tissue reaction, device failure, adverse interaction with other devices, user error, vessel damage, and infection. The draft guidance document entitled "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" aids in mitigating the risks through recommendations on biocompatibility, performance and animal testing, clinical information, sterilization, shelf life, and labeling.

A. Adverse Tissue Reaction

Materials used to manufacture PTCA catheters may cause adverse tissue reactions in the patient, such as localized cell death, irritation, hemolysis, complement activation, thrombus formation, and febrile reactions.

B. Device Failure

Balloon burst or rupture can be caused by over-inflation of the balloon during the procedure, use of a defective balloon, improper balloon sizing, the use of improper balloon inflation medium, or tissue calcification. PTCA catheter shaft breakage can be caused by failure of the manufacturing bonds or by use of excessive force during the procedure. Device failure may lead to reaction to contrast agent, vessel damage, air embolism, stroke, aneurysm formation, need for emergency bypass surgery or death.

C. Adverse Interaction with Other Devices

PTCA catheters are used with accessory devices such as introducers, guiding catheters, and guidewires. Use with incompatible devices may result in a failed PTCA procedure and adverse clinical consequences. Guidewire entrapment or fragmentation by a PTCA catheter may lead to vessel damage, acute MI, unstable angina, coronary artery spasm, or arrhythmias, and is usually caused by excessive tortuosity of the coronary vessels or a complex coronary vascular anatomy.

D. User Error

Operator inexperience and improper use of the device are common contributors to failed PTCA procedures. Examples of improper use include over-inflation of the balloon, improper balloon sizing, excessively slow

deflation of the balloon, use of excessive force during the procedure, and improper balloon delivery or retraction.

During a PTCA procedure it is possible that air embolization may occur as a result of incomplete aspiration of the guiding catheter, balloon rupture, or insinuation of air with the PTCA catheter during insertion or withdrawal. Air embolization may cause a stroke.

The risk of vascular access site complications, including hematomas, arteriovenous (A-V) fistulas, infections, and pseudoaneurysms may be the result of the use of excessive force during the procedure, difficulty placing the device, inadequate treatment of the access site following the procedure, puncture of an adjacent artery and vein, or inadequate aseptic techniques.

E. Vessel Damage

Injury to the coronary vessel wall, resulting in dissection, perforation, or rupture, is a risk that can occur with any PTCA procedure. Vessel damage may be caused by balloon rupture or burst, perforation or rupture of the vessel with an accessory device (e.g., guidewire or catheter), inappropriate balloon sizing, and expansion of an intramural hematoma. Vessel damage may lead to acute vessel closure, acute MI, unstable angina, coronary artery spasm, embolization or fragmentation of thrombotic or atherosclerotic material, or aneurysm formation.

F. Infection

Infection may be caused by contamination of the device prior to use or inadequate aseptic techniques.

VI. Summary of the Reasons for the Recommendation

After considering the data and information contained in the petition and provided by FDA, the open discussion during the Panel meeting, and their

knowledge of and clinical experience with the device, the Panel gave the following reasons in support of its recommendation to reclassify PTCA catheters from class III to class II, except when indicated for the treatment of in-stent restenosis and/or post-deployment stent expansion. The Panel believed that the devices should be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

The Panel recommended that PTCA catheters for the treatment of in-stent restenosis and/or post-deployment stent expansion not be included because of a lack of sufficient information about this use. Since the Panel meeting, however, additional data regarding this use have become available and have been reviewed by the agency (see section IX of this document, FDA's Findings).

VII. Summary of Data Upon Which the Panel Recommendation is Based

Based on the information discussed during the on December 4, 2000, Panel meeting, information presented in the reclassification petition, published literature, and medical device reports, the Panel believes there is reasonable knowledge of the benefits of the device. PTCA catheters provide a minimally invasive means of treating coronary artery disease and may be a less traumatic alternative to coronary artery bypass surgery in some patients.

VIII. Special Controls

In addition to general controls, FDA believes that the draft guidance entitled "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters," along with general controls, would address the risks to health associated with the use of the device described in section V of this document. The draft class II special controls guidance document references voluntary consensus standards

and describes testing and labeling recommendations intended to address the Panel's concerns. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft class II special controls guidance document that the agency intends to use as the special control for this device type.

The draft class II special controls guidance document contains specific recommendations with regard to device performance testing and other information that FDA believes should be included in premarket (510(k)) notification submissions for PTCA catheters. Particular sections of the draft guidance document address the following topics: Biocompatibility testing, performance testing, animal testing, clinical information, labeling, sterilization, and sterilization and shelf life.

In Table 1 of this document, FDA has identified the risks to health associated with the use of the device in the first column and the recommended mitigation measures identified in the class II special controls guidance document in the second column. These recommendations will also help ensure that the device has appropriate performance characteristics and labeling for its use.

Following the effective date of any final reclassification rule based on this proposal, any firm submitting a 510(k) submission for a PTCA catheter will need to address the issues covered in the class II special controls guidance document. However, the firm need only show that its device meets the recommendations of the class II special controls guidance document or in some other way provides equivalent assurances of safety and effectiveness.

TABLE 1.

Identified Risk	Recommended Mitigation Measures
Adverse Tissue Reaction	Biocompatibility Testing

TABLE 1.—Continued

Identified Risk	Recommended Mitigation Measures
Device Failure	Performance Testing Sterilization and Shelf Life
Adverse Interaction With Other Devices	Performance Testing Animal Testing
User Error	Animal Testing Clinical Information Labeling
Vessel Damage	Animal Testing Clinical Information
Infection	Sterilization and Shelf Life

IX. FDA's Findings

The Panel and FDA believe that PTCA catheters, other than cutting/scoring PTCA catheters, should be reclassified from class III into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

The Panel recommended a guidance document, labeling, and postmarket surveillance as special controls. Although the Panel included the possibility of requiring postmarket surveillance in their recommendation, FDA does not believe that specific postmarket surveillance such as device tracking or postapproval studies are needed for PTCA catheters. FDA believes that periodic assessment of adverse event reports through medical device reporting submitted to the agency is sufficient to address adverse effects caused by these devices and is the least burdensome way to gather this data for PTCA catheters. This practice is consistent with the manner in which these devices have been regulated as class III devices since the Panel meeting.

Further, after a review of adverse event reports submitted to FDA's Manufacturer and User Facility Device Experience (MAUDE) Database (Ref. 3), the agency believes that the types of risks associated with the use of PTCA catheters for the treatment of in-stent restenosis and/or post-deployment stent

expansion are similar enough to the risks associated with treatment of de novo lesions, such that the special controls discussed at the Panel meeting, with the addition of recommendations for specific nonclinical performance testing and the recommendation that in-stent restenosis patients be included in the clinical evaluation, when necessary, are adequate to control the risks to health for these devices.

X. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday:

1. Petition for Reclassification of Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters submitted by COOK, Inc., Lafayette, IN, received September 12, 2000.
2. Transcript of the Circulatory System Devices Panel Meeting, December 4, 2000, vol. I, pp. 1–282.
3. FDA's Manufacturer and User Facility Device Experience (MAUDE) Database is publicly accessible at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Search.cfm>. Enter product code LOX to search for reports regarding PTCA catheters.

XI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. Analysis of Impacts

FDA has examined the impacts of the reclassification action under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612),

and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this reclassification action is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of the device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act, the agency certifies that this reclassification action will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this reclassification action to result in any 1-year expenditure that would meet or exceed this amount.

XIII. Federalism

FDA has analyzed this reclassification action in accordance with the principles set forth in Executive Order 13132. FDA has determined that the reclassification action does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the reclassification action does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XIV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this reclassification action contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the draft special control guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance document entitled “Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters;” the notice contains an analysis of the paperwork burden for the draft guidance.

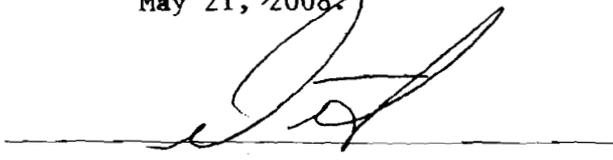
XV. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed

comments, except that individuals may submit one paper copy. Comments are to be identified with the name of the device and the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only at *<http://www.regulations.gov>*.

Dated: 5/21/08
May 21, 2008.



Daniel G. Schultz,
Director,
Center for Devices and Radiological Health.

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