



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA-2012-N-0303]

Gastroenterology-Urology Devices; Reclassification of Implanted Blood Access Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed administrative order to reclassify the implanted blood access device preamendments class III device into class II (special controls) and subject to premarket notification, and to further clarify the identification.

FDA is proposing this reclassification under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) based on new information pertaining to the device. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments on the proposed order by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section XII for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0303, 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:

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

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-0303 for this order. 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 "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: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1540, Silver Spring, MD 20993, 301-796-6527.

### SUPPLEMENTARY INFORMATION:

#### I. Background--Regulatory Authorities

The FD&C Act establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three

categories (classes) of devices, reflecting 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).

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C 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, in accordance with section 513(i) of the FD&C 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 FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended the device reclassification procedures under section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Prior to the enactment of

FDASIA, FDA published a proposed rule under section 513(e) proposing the reclassification of implanted blood access devices for hemodialysis (77 FR 36951; June 20, 2012). FDA is issuing this proposed administrative order to comply with the new procedural requirement created by FDASIA when reclassifying a preamendments class III device. Also as required by section 513(e) of the FD&C Act, FDA has scheduled a panel meeting to discuss the proposed reclassification for June 27, 2013 (78 FR 25747; May 2, 2013). The three comments submitted in response to the proposed rule on implanted blood access devices for hemodialysis will be considered under this proposed administrative order and do not need to be resubmitted. No objections to the proposed reclassification were submitted. This action is intended solely to fulfill the procedural requirements for reclassification implemented by FDASIA. FDA is also issuing the draft guidance, "Implanted Blood Access Devices for Hemodialysis," which provides recommendations on how to comply with the special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the device.

Section 513(e) of the FD&C Act provides that FDA may, by administrative order, reclassify a device based upon "new information." FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA to reclassify a preamendments device. The term "new information," as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., Holland-Rantos Co. v. United States Dep't of Health, Educ., & Welfare, 587 F.2d 1173, 1174 n.1 (DC Cir. 1978); Upjohn v. Finch, 422 F.2d 944 (6th Cir. 1970); Bell v. Goddard, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see Bell v. Goddard, supra, 366 F.2d at 181; Ethicon, Inc. v. FDA, 762 F.Supp. 382, 388-391 (D.D.C. 1991)), or in light of changes in "medical science." (See Upjohn v. Flinch supra, 422 F.2d at 951.) Whether data before the Agency are old or new data, the "new information" to support reclassification under section 513(e) must be "valid scientific evidence," as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, e.g., General Medical Co. v. FDA, 770 F.2d 214 (DC Cir. 1985); Contact Lens Association v. FDA, 766 F.2d 592 (DC Cir. 1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the valid scientific evidence upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application (PMA). (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by the Food and Drug Administration Modernization Act of 1997 (FDAMA), provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device, but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the Federal Register; (2) a meeting of a device

classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments from all affected stakeholders, including patients, payors, and providers. In addition, the proposed order must set forth the proposed reclassification, and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including the public health benefits of the use of the device, and the nature and incidence (if known) of the risk of the device. (See section 513(e)(1)(A)(i) of the FD&C Act.)

FDAMA added section 510(m) to the FD&C Act. Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

## II. Regulatory History of the Device

As discussed in the preamble to the proposed rule (46 FR 7616; January 23, 1981), the Gastroenterology-Urology Devices Panel recommended that both implanted and nonimplanted blood access devices be classified into class II. Although FDA agreed with the panel recommendation for nonimplanted blood access devices, FDA disagreed with the panel for implanted blood access devices and proposed that implanted blood access devices be classified into class III because FDA believed that the device presented a potential unreasonable risk of illness or injury to the patient. FDA also noted that the implanted blood access device is part of a life-supporting and life-sustaining system and that general controls and performance standards were insufficient to provide reasonable assurance of the safety and effectiveness of implanted blood access devices.

In 1983, FDA classified implanted blood access devices into class III, but the accessories to these devices into class II (48 FR 53012; November 23, 1983). In 1987, FDA published a

clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for implanted blood access devices (52 FR 17732 at 17738; May 11, 1987).

In 2009, FDA published an order for the submission of information on implanted blood access devices (74 FR 16214; April 9, 2009). In response to that order, FDA received information in support of reclassification from 15 device manufacturers who all recommended that implanted blood access devices be reclassified to class II. The manufacturers stated that safety and effectiveness of these devices may be assured by bench testing, biocompatibility testing, sterility testing, expiration date testing, labeling, and standards.

On June 20, 2012, FDA published a proposed rule proposing the reclassification of implanted blood access devices for hemodialysis from class III to class II (77 FR 36951) and announced the availability of a draft Special Controls Guidance Document that, when finalized, would serve as a special control, if FDA reclassified these devices. FDA believed that the special controls as described in the guidance document entitled "Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis" would be sufficient to mitigate the risks to health associated with implanted blood access devices for hemodialysis.

The proposed rule provided for a comment period that was open until September 18, 2012. FDA received three comments that suggested modifications to the proposed Special Controls Guidance Document. These were considered by FDA.

On July 9, 2012, FDASIA was enacted, which amended the device reclassification procedures under sections 513 and 515 of the FD&C Act (21 U.S.C. 360c and 360e, respectively), changing the process for taking final administrative action for these devices. Accordingly, FDA is issuing a proposed administrative order to comply with the new procedural requirement cre-

ated by FDASIA when reclassifying a preamendments class III device. Further, FDA intends to codify the proposed special controls within the § 876.5540(b)(1) (21 CFR 876.5540(b)(1)) classification regulation.

### III. Device Description

Implanted blood access devices include various flexible or rigid tubes, such as catheters or cannulae. Chronic hemodialysis catheters are soft, blunt-tipped plastic catheters that have a subcutaneous "cuff" for tissue ingrowth. They are placed in a central vein to allow blood access. Chronic hemodialysis catheters serve as conduits for the removal of blood from the patient, delivery to a hemodialysis machine for filtering, and return of filtered blood to the patient. They have no moving parts, consisting, essentially, of flexible tubing terminating in rigid Luer lock connectors for attachment to a dialysis machine. Subcutaneous catheters are totally implanted below the skin surface with no external communication. Arteriovenous shunts and vessel tips are tubing with tapered tips that are inserted into the artery and vein. The tubing is attached to the roughened or etched outer surface of the tip. The tubing is external to the skin and can be accessed with needles.

FDA is proposing in this order to modify the identification language from how it is presently written in § 876.5540(a)(1) for additional clarification. FDA is clarifying in the identification that these are prescription devices and modifying the examples of devices (e.g., catheter, cannulae) in the identification language to be consistent with existing legally marketed devices covered by this classification.

### IV. Proposed Reclassification

FDA is proposing that implanted blood access devices for hemodialysis be reclassified from class III to class II. In this proposed order, the Agency has identified special controls under



section 513(a)(1)(B) of the FD&C Act that, together with general controls (including prescription-use restrictions) applicable to the devices, would provide reasonable assurance of their safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA believes that this new information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in the next section, and that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness for implanted blood access devices.

FDA believes that these devices can be utilized to provide access to a patient's blood for hemodialysis or other chronic uses for 30 days or more. When used in hemodialysis, the device is part of an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and provides access to a patient's blood for hemodialysis.

FDA has considered implanted blood access devices in accordance with the reserved criteria set forth in section 510(l) and decided that the device requires premarket notification (510(k) of the FD&C Act). Therefore, the Agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submission as provided under section 510(m) of the FD&C Act.

## V. Risks to Health

After considering available information for the classification of these devices, FDA has evaluated the risks to health associated with the use of implanted blood access devices for hemodialysis and determined the following risks to health are associated with its use:

- Thrombosis in patient and catheter occlusion, or central venous stenosis. Inadequate blood compatibility of the materials used in this device, blood pooling between dialysis sessions,

or turbulent blood pathways could lead to potentially debilitating or fatal thromboembolism.

- Adverse tissue reaction. Inadequate tissue compatibility of the materials used in this device could cause an immune reaction.
- Infection and pyrogen reactions. An improperly sterilized device could cause a skin or bloodstream infection.
- Device failure. Weakness of connections or materials could lead to blood loss or device fragment embolization.
- Cardiac arrhythmia, hemorrhage, embolism, nerve injury, or vessel perforation. Improper placement into the heart or blood vessel could damage tissues and result in injuries.
- Hemolysis. Turbulence or high pressure created by narrow openings or changes in blood flow paths could cause the destruction of red blood cells.
- Accidental withdrawal or catheter migration. A catheter's cuff may not allow adequate ingrowth from the surrounding subcutaneous tissue, which could cause the device to dislodge or fall out with subsequent blood loss.

## VI. Summary of Reasons for Reclassification

FDA believes that implanted blood access devices for hemodialysis should be reclassified from class III to class II because special controls, in addition to general controls, can be established to provide reasonable assurance of the safety and effectiveness of the device, and because general controls themselves are insufficient to provide reasonable assurance of its safety and effectiveness. In addition, there is now sufficient information to establish special controls to provide such assurance.

While current clinical practice guidelines recommend avoiding implanted blood access devices, such as catheters, if possible, they are still a necessary treatment option, and are used in

a significant number of hemodialysis patients. While the risks are frequently cited, there are many advantages of implanted blood access devices, which lead to their relatively frequent use, as described previously. In many cases, vascular access for hemodialysis is needed urgently, and the alternatives, such as the arteriovenous fistula or the arteriovenous graft require weeks and months, respectively, before they can be used. Implanted blood access devices are frequently used as the immediate hemodialysis vascular access and also as a bridge to a more permanent vascular access. Additionally, some patients may have inadequate vascular anatomy to establish a more permanent vascular access and may require continued implanted blood access device use.

#### VII. Summary of Data Upon Which the Reclassification Is Based

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of these devices. Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and § 860.130, based on new information with respect to the device and taking into account the public health benefit of the use of the device and the nature and known incidence of the risk of the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. The Agency has identified special controls that would provide reasonable assurance of their safety and effectiveness. Implanted blood access devices for hemodialysis are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device (proposed § 876.5540(a); § 801.109 (21 CFR 801.109) (Prescription devices.)).

Since 1983 when FDA classified implanted blood access devices into class III, sufficient evidence has been developed to support a reclassification to class II with special controls. FDA has been reviewing these devices for many years and their risks are well known. The risks to

health are identified in section V, and FDA believes these risks can be adequately mitigated by special controls. Catheters continue to evolve over time with improved materials and insertion techniques to mitigate the risks. A review of 15 publications shows a decrease in infections and an increase in patency over three decades (1980 to 2011) (Refs. 1 to 15). The decrease in occurrence of serious adverse events as evidenced through FDA's Manufacturer and User Facility Device Experience (MAUDE) database, the valid scientific evidence to support implanted blood access devices for hemodialysis provided in the referenced publications, and FDA's review experience with these devices, supports FDA's conclusion that the identified special controls, including performance testing demonstrating that the device performs as intended under anticipated conditions of use, is appropriately designed, and includes adequate safeguards and labeling to inform users of inappropriate use conditions, in addition to general controls, provide reasonable assurance of the safety and effectiveness of implanted blood access devices.

#### VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls (including applicable prescription-use restrictions and continuing 510(k) notification requirements), are sufficient to mitigate the risks to health described in section V for implanted blood access devices:

1. Components of the device that come into human contact must be demonstrated to be biocompatible. Material names and specific designation numbers must be provided.
2. Performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

- a. Pressure versus flow rates for both arterial and venous lumens, from the minimum flow rate to the maximum flow rate in 100 ml/min increments, must be established. The fluid and its viscosity used during testing must be stated.
  - b. Recirculation rates for both forward and reverse flow configurations must be established, along with the protocol used to perform the assay, which must be provided.
  - c. Priming volumes must be established.
  - d. Tensile testing of joints and materials must be conducted. The minimum acceptance criteria must be adequate for its intended use.
  - e. Air leakage testing and liquid leakage testing must be conducted.
  - f. Testing of the repeated clamping of the extensions of the catheter that simulates use over the life of the catheter must be conducted, and retested for leakage.
  - g. Mechanical hemolysis testing must be conducted.
  - h. Chemical tolerance of the catheter to repeated exposure to commonly used disinfection agents must be established.
3. Performance data must demonstrate the sterility of the device.
4. Performance data must support the shelf life of the device for continued sterility, package integrity, and functionality over the requested shelf life that must include tensile, repeated clamping, and leakage testing.
5. Labeling must bear all information required for the safe and effective use of implanted blood access devices for hemodialysis including the following:
  - a. Labeling must provide arterial and venous pressure versus flow rates, either in tabular or graphical format.

- b. Labeling must provide the arterial and venous priming volumes.
  - c. Labeling must specify the forward and reverse recirculation rates.
  - d. Labeling must specify an expiration date.
  - e. Labeling must identify any disinfecting agents that cannot be used to clean any components of the device.
  - f. Any contraindicated disinfecting agents due to material incompatibility must be identified by printing a warning on the catheter. Alternatively a label can be provided that can be affixed to the patient's medical record with this information.
  - g. The labeling must contain the following information: Comprehensive instructions for the preparation and insertion of the hemodialysis catheter, including recommended site of insertion, method of insertion, a reference on the proper location for tip placement, a method for removal of the catheter, anticoagulation, guidance for management of obstruction and thrombus formation, and site care.
  - h. The labeling must identify any coatings or additives and summarize the results of performance testing for any coating or material with special characteristics, such as decreased thrombus formation or antimicrobial properties.
6. For subcutaneous devices, the recommended type of needle for access must be described, stated in the labeling, and test results on repeated use of the ports must be provided.
7. Coated devices must include a description of the coating or additive material, duration of effectiveness, how the coating is applied, and testing to adequately demonstrate the performance of the coating.

In addition, implanted blood access devices are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device.

(Proposed § 876.5540(a); § 801.109 (Prescription devices.)). Under 21 CFR 807.81, the device would continue to be subject to 510(k) notification requirements. Elsewhere in this issue of the Federal Register, FDA is announcing the availability of a draft guidance document entitled "Implanted Blood Access Devices for Hemodialysis," that, when finalized, would provide recommendations on how to comply with the special controls proposed in this order, if FDA reclassifies this device (Ref. 16).

#### IX. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action 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.

#### X. Paperwork Reduction Act of 1995

This proposed order refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910-0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

#### XI. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in

the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i), as amended by FDASIA, in this proposed order we are proposing to revoke the requirements in § 876.5540(b)(1) related to the classification of implanted blood access devices as class III devices and to codify the reclassification of implanted blood access devices into class II (special controls).

## XII. Proposed Effective Date

FDA is proposing that any final order based on this proposed order become effective on the date of its publication in the Federal Register or at a later date if stated in the final order.

## XIII. Comments

Comments submitted to the previous dockets (2012-N-0303) have been officially noted and do not need to be resubmitted. FDA will consider previous docket comments in issuing any final orders for these devices. Interested persons may submit either electronic comments regarding this document or the associated guidance to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with 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, and will be posted to the docket at <http://www.regulations.gov>.

## XIV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.



1. Eisenhauer, E.D., R.J. Derveloy, and P.R. Hastings, "Prospective Evaluation of Central Venous Pressure (CVP) Catheters in a Large City-County Hospital," Annals of Surgery, vol. 196, pp. 560-564, 1982.
2. Vanholder, V., N. Hoenich, and S. Ringoir, "Morbidity and Mortality of Central Venous Catheter Hemodialysis: A Review of 10 Years' Experience," Nephron, vol. 47, pp. 274-279, 1987.
3. Almirall, J., J. Gonzalez, J. Rello, et al., "Infection of Hemodialysis Catheters: Incidence and Mechanisms," American Journal of Nephrology, vol. 9, pp. 454-459, 1989.
4. Boyle, M.J., W.F. Gawley, D.P. Hickey, et al., "Experience Using the Quinton Permcath for Haemodialysis in the Irish Republic," Nephrology Dialysis Transplantation, vol. 12, pp. 1934-1939, 1997.
5. Randolph, A.G., D.J. Cook, C.A. Gonzales, et al., "Ultrasound Guidance for Placement of Central Venous Catheters: A Meta-Analysis of the Literature," Critical Care Medicine, vol. 24, pp.2053-2058, 1996.
6. Arnold, W.P., "Improvement in Hemodialysis Vascular Access Outcomes in a Dedicated Access Center," Seminars in Dialysis, vol. 13, pp. 359-363, 2000.
7. Wivell, W., M.A. Bettmann, B. Baxter, et al., "Outcomes and Performance of the Tesio Twin Catheter System Placed for Hemodialysis Access," Radiology, vol. 221, pp. 697-703, 2001.
8. Lund, G.B., S.O. Trerotola, P.F. Scheel, Jr, et al., "Outcome of Tunneled Hemodialysis Catheters Placed by Radiologists," Radiology, vol. 198, pp. 467-472, 1996.
9. Trerotola, S.O., M.S. Johnson, V.J. Harris, et al., "Outcome of Tunneled Hemodialysis Catheters Placed via the Right Internal Jugular Vein by Interventional Radiologists,"

Radiology, vol. 203, pp. 489-495, 1997.

10. Prabhu, P.N., S.R. Kerns, F.W. Sabatelli, et al., "Long-Term Performance and Complications of the Tesio Twin Catheter System for Hemodialysis Access," American Journal of Kidney Diseases, vol. 30, pp. 213-218, 1997.
11. Schnabel, K.J., M.E. Simons, G.F. Zevallos, et al., "Image-Guided Insertion of the Uldall Tunneled Hemodialysis Catheter: Technical Success and Clinical Follow-Up," Journal of Vascular and Interventional Radiology, vol. 8, pp.579-586, 1997.
12. Nassar, G.M. and J.C. Ayus, "Infectious Complications of the Hemodialysis Access," Kidney International, vol. 60, pp. 1-13, 2001.
13. Power, A., S.K. Singh, D. Ashby, et al., "Long-term Tesio Catheter Access for Hemodialysis Can Deliver High Dialysis Adequacy With Low Complication Rates," Journal of Vascular and Interventional Radiology, vol. 22, pp. 631-637, 2011.
14. Duncan, N.D., S. Singh, T.D. Cairns, et al., "Tesio-Caths Provide Effective and Safe Long-Term Vascular Access," Nephrology Dialysis Transplantation, vol. 19, pp. 2816-2822, 2004.
15. Eisenstein, I., M. Tarabeih, D. Magen, et al., "Low Infection Rates and Prolonged Survival Times of Hemodialysis Catheters in Infants and Children," Clinical Journal of the American Society of Nephrology, vol. 6, pp. 793-798, 2011.
16. Draft guidance entitled "Implanted Blood Access Devices for Hemodialysis," available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>.

#### List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 876 be amended as follows:

#### PART 876--GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 876.5540 is amended by revising paragraphs (a)(1), (b)(1), and by removing paragraph (c) to read as follows:

#### § 876.5540 Blood access device and accessories.

(a) \* \* \*

(1) The implanted blood access device is a prescription device and consists of various flexible or rigid tubes, such as catheters, or cannulae, which are surgically implanted in appropriate blood vessels, may come through the skin, and are intended to remain in the body for 30 days or more. This generic type of device includes: Single, double, and triple lumen catheters with cuffs; subcutaneous ports with catheters; shunts; cannula; vessel tips; and connectors specifically designed to provide access to blood.

\* \* \* \* \*

(b) Classification. (1) Class II (special controls) for the implanted blood access device.

The special controls for this device are:

(i) Components of the device that come into human contact must be demonstrated to be biocompatible. Material names and specific designation numbers must be provided.

(ii) Performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(A) Pressure versus flow rates for both arterial and venous lumens, from the minimum flow rate to the maximum flow rate in 100 ml/min increments, must be established. The fluid and its viscosity used during testing must be stated.

(B) Recirculation rates for both forward and reverse flow configurations must be established, along with the protocol used to perform the assay, which must be provided.

(C) Priming volumes must be established.

(D) Tensile testing of joints and materials must be conducted. The minimum acceptance criteria must be adequate for its intended use.

(E) Air leakage testing and liquid leakage testing must be conducted.

(F) Testing of the repeated clamping of the extensions of the catheter that simulates use over the life of the catheter must be conducted, and retested for leakage.

(G) Mechanical hemolysis testing must be conducted.

(H) Chemical tolerance of the catheter to repeated exposure to commonly used disinfection agents must be established.

(iii) Performance data must demonstrate the sterility of the device.

(iv) Performance data must support the shelf life of the device for continued sterility, package integrity, and functionality over the requested shelf life that must include tensile, repeated clamping, and leakage testing.

(v) Labeling must bear all information required for the safe and effective use of implanted blood access devices for hemodialysis including the following:

(A) Labeling must provide arterial and venous pressure versus flow rates, either in tabular or graphical format.

(B) Labeling must provide the arterial and venous priming volumes.

(C) Labeling must specify the forward and reverse recirculation rates.

(D) Labeling must specify an expiration date.

(E) Labeling must identify any disinfecting agents that cannot be used to clean any components of the device.

(F) Any contraindicated disinfecting agents due to material incompatibility must be identified by printing a warning on the catheter. Alternatively a label can be provided that can be affixed to the patient's medical record with this information.

(G) The labeling must contain the following information: Comprehensive instructions for the preparation and insertion of the hemodialysis catheter, including recommended site of insertion, method of insertion, a reference on the proper location for tip placement, a method for removal of the catheter, anticoagulation, guidance for management of obstruction and thrombus formation, and site care.

(H) The labeling must identify any coatings or additives and summarize the results of performance testing for any coating or material with special characteristics, such as decreased thrombus formation or antimicrobial properties.

(vi) For subcutaneous devices, the recommended type of needle for access must be described, stated in the labeling, and test results on repeated use of the ports must be provided.

(vii) Coated devices must include a description of the coating or additive material, duration of effectiveness, how the coating is applied, and testing to adequately demonstrate the performance of the coating.

\* \* \* \* \*

Dated: June 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-15504 Filed 06/27/2013 at 8:45 am; Publication Date: 06/28/2013]