

Brief Summary of the Gastroenterology-Urology Devices Panel Meeting

June 27, 2013

The Gastroenterology-Urology Devices Panel met on June 27, 2013 to make recommendations regarding the possible reclassification of implanted blood access devices for hemodialysis from class III to class II. The Panel's discussion involved making recommendations regarding regulatory classification to either reaffirm class III or reclassify these devices into class II and comment on whether special controls can be established to reasonably ensure the safety and effectiveness of these devices.

Panel Deliberations/FDA Questions:

The panel believed that blood access devices for hemodialysis are life sustaining/life supporting and are of substantial importance in preventing impairment of human health. The panel members agreed that general controls are not sufficient.

During the panel deliberations, the Panel concluded that it would be acceptable to reclassify the implanted hemodialysis catheters and the implanted coated hemodialysis catheters into Class II with the slight modifications to the proposed Special Controls as described below.

The panel did not agree that the risks associated with the fully subcutaneous implanted blood access devices (port catheter systems) or the arteriovenous (A-V) shunt cannulae could be mitigated by special controls in order to provide a reasonable assurance of safety and effectiveness. The Panel recommended that these two implanted blood access device subtypes remain in Class III.

The panel was asked to comment on the following risks to health:

- Thrombosis in patient and catheter occlusion, or central venous stenosis
- Adverse tissue reaction
- Infection and pyrogen reactions
- Device failure
- Cardiac arrhythmia, hemorrhage, embolism, nerve injury, or vessel perforation
- Hemolysis
- Accidental withdrawal or catheter migration

The panel agreed with the above risks to health and proposed the following additions:

- For A-V Shunt cannulae, add arterial thrombosis (in addition to venous thrombosis), premature separation and bleeding, potential for exsanguination, air embolism, and steal syndrome
- Add that improper insertion, care, or maintenance of catheters can also lead to infection
- Add anaphylaxis as a risk for drug-coated devices
- Consider adding death as a potential risk

The panel was asked to comment on the following proposed special controls:

- Biocompatibility
- Performance data:
 - Pressure versus flow, recirculation, priming volumes, tensile testing of joints and materials, air and liquid leakage testing, repeated clamping of the catheter extensions, mechanical hemolysis, chemical tolerance to repeated exposure to commonly used disinfection agents, sterility, and shelf-life
- Labeling:
 - Pressure versus flow rates, priming volumes, recirculation rates, expiration date, appropriate disinfecting agents, comprehensive insertion instructions, anticoagulation recommendations, guidance for management of obstruction/thrombus, and site care
 - Coatings or additives should be identified and results of coating performance testing should be summarized
- For subcutaneous devices, the recommended needle type must be described, stated in the labeling, and test results on repeated use of the ports must be provided.
- Coated devices must include a description of the coating, duration of effectiveness, how the coating is applied, and testing to adequately demonstrate coating performance.

The panel members had the following additional suggestions:

- Performance data should demonstrate how anticoagulant or antimicrobial lock solutions interact with catheter materials
- Special controls for the fully subcutaneous and coated devices should be expanded to require clinical performance data to support claims about antithrombotic and antimicrobial properties. It was suggested that post-market studies could be added as a special control, but this requirement should be balanced with pre-market clinical studies as to not be overly burdensome.
- Special controls for the labeling should also include language regarding qualified physicians, repair kits, appropriate barriers between uses, maintenance of catheter patency, good medical practice guidelines, and clearly stated purpose of coatings (if present). It was suggested that the labeling should include online videos demonstrating catheter use.

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