

# 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 sorbent hemoperfusion systems indicated for the treatment of poisoning and drug overdose from class III to class II, while maintaining the class III classification for hemoperfusion systems intended to treat hepatic coma and metabolic disturbances. The Panel's discussion involved making recommendations regarding regulatory classification for each of these indications, and comment on whether special controls can be established to reasonably ensure the safety and effectiveness of the devices for the indications proposed for reclassification.

## Panel Deliberations/FDA Questions

The panel believed that hemoperfusion systems are life-sustaining/life-supporting and are of substantial importance in preventing impairment of human health. The panel agreed that general controls are not sufficient.

During the panel deliberations, the panel concluded that it would be acceptable to reclassify hemoperfusion systems indicated for treatment of poisoning and drug overdose into class II with the special controls as described below.

The panel agreed with the FDA recommendation that hemoperfusion systems indicated for the treatment of hepatic coma and metabolic disturbances remain in class III because of the scarcity of literature data supporting this indication and that special controls could not be established for these indications.

The panel was asked to comment on the following Risks to Health for all indications of sorbent hemoperfusion systems:

- Extracorporeal leaks (blood loss)
- Platelet loss and thrombocytopenia
- Leukopenia
- Hemolysis
- Leak of adsorbent agent into fluid path (release of emboli)
- Lack of sterility
- Toxic and/or pyrogenic reactions
- Infection
- Hypotension
- Lack of biocompatibility
- Clotting (blood loss)
- Removal or depletion of vital nutrients, hormones, vitamins, substances, and drugs (e.g., adsorption of glucose, unspecific removal characteristics, drop in patients' hematocrit), due to device's lack of specificity
- Metabolic Disturbances
- Lack of effectiveness
- Treatment interruptions or discontinuation
- Electrical shock due to lack of electrical safety

- Electromagnetic interference

The panel agreed with the above risks to health.

The panel was asked to comment on the following special controls for sorbent hemoperfusion systems indicated for drug overdose or poisoning:

- The device must be demonstrated to be biocompatible;
- Performance data to demonstrate the mechanical integrity of the device (e.g., tensile, flexural, and structural strength), including testing for the possibility of leaks, ruptures, release of particles, and/or disconnections;
- Performance data to demonstrate device sterility and shelf life;
- Bench performance data to demonstrate device functionality in terms of substances, toxins, and drugs removed by the device, and the extent that these are removed when the device is used according to its labeling, and to validate the device's safeguards;
- Summary of clinical experience with the device that discusses and analyzes device safety and performance, including a list of adverse events observed during the testing;
- Labeling controls, including appropriate warnings, precautions, cautions, and contraindications statements to alert and inform users of proper device use and potential clinical adverse effects, including blood loss, platelet loss, leukopenia, hemolysis, hypotension, clotting, metabolic disturbances, and loss of vital nutrients and substances; labeling recommendations must be consistent with the performance data obtained for the device, and must include a list of the drugs and/or poisons the device has been demonstrated to remove, and the extent for removal/depletion; and
- For those devices that incorporate electrical components, appropriate analysis and testing to validate electrical safety and electromagnetic compatibility

The panel agreed that these special controls would be sufficient to reclassify hemoperfusion systems indicated for *poisoning and drug overdose* to be reclassified into class II.

For hemoperfusion systems indicated for the treatment of hepatic coma and metabolic disturbances, the panel agreed that the special controls presented above would not be sufficient to assure the safety and effectiveness of the devices if reclassified into class II and recommended that, for these indications, the devices remain class III.

**Contact: Shanika Craig, MHA, MBA**

**Designated Federal Officer, (301) 796- 6639**

**[Shanika.Craig@fda.hhs.gov](mailto:Shanika.Craig@fda.hhs.gov)**

**Transcripts may be purchased from: (written requests only)**

**Free State Reporting, Inc.**

**1378 Cape St. Claire Road**

**Annapolis, MD 21409**

**410-974-0947**

**or**

**800-231-8973 Ext. 103 410-974-0297 fax Or**

**Food and Drug Administration**

**Freedom of Information Staff (FOI)**

**5600 Fishers Lane, HFI-35**

**Rockville, MD 20851**

**(301) 827-6500 (voice), (301) 443-1726**