

(i) The device must be demonstrated to be biocompatible;

(ii) Performance data must 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 under anticipated conditions of use;

(iii) Performance data must demonstrate device sterility and shelf life;

(iv) Bench performance testing must 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;

(v) A 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, must be provided;

(vi) Labeling must include the following:

(A) A detailed summary of the device-related and procedure-related complications pertinent to the use of the device;

(B) A summary of the performance data provided for the device, including a list of the drugs and/or poisons the device has been demonstrated to remove, and the extent for removal/depletion; and

(vii) For those devices that incorporate electrical components, appropriate analysis and testing must be conducted to verify electrical safety and electromagnetic compatibility of the device.

(2) Class III (premarket approval) when the device is intended for the treatment of hepatic coma and metabolic disturbances.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with FDA by April 17, 2014, for any sorbent hemoperfusion system indicated for treatment of hepatic coma or metabolic disturbances that was in commercial distribution before May 28, 1976, or that has, by April 17, 2014, been found to be substantially equivalent to any

sorbent hemoperfusion device indicated for treatment of hepatic coma or metabolic disturbances that was in commercial distribution before May 28, 1976. Any other sorbent hemoperfusion system device indicated for treatment of hepatic coma or metabolic disturbances shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[79 FR 3094, Jan. 17, 2014]

§ 876.5880 Isolated kidney perfusion and transport system and accessories.

(a) *Identification.* An isolated kidney perfusion and transport system and accessories is a device that is used to support a donated or a cadaver kidney and to maintain the organ in a near-normal physiologic state until it is transplanted into a recipient patient. This generic type of device may include tubing, catheters, connectors, an ice storage or freezing container with or without bag or preservatives, pulsatile or nonpulsatile hypothermic isolated organ perfusion apparatus with or without oxygenator, and disposable perfusion set.

(b) *Classification.* Class II (performance standards).

§ 876.5885 Tissue culture media for human ex vivo tissue and cell culture processing applications.

(a) *Identification.* Tissue culture media for human ex vivo tissue and cell culture processing applications consist of cell and tissue culture media and components that are composed of chemically defined components (e.g., amino acids, vitamins, inorganic salts) that are essential for the ex vivo development, survival, and maintenance of tissues and cells of human origin. The solutions are indicated for use in human ex vivo tissue and cell culture processing applications.

(b) *Classification.* Class II (special controls): FDA guidance document, "Class II Special Controls Guidance Document: Tissue Culture Media for Human Ex Vivo Processing Applications; Final Guidance for Industry and FDA Reviewers."

[66 FR 27025, May 16, 2001]