warnings. Labeling must include identification of compatible introducer needles.

[79 FR 13219, Mar. 10, 2014]

§ 878.4760 Removable skin staple.

(a) *Identification.* A removable skin staple is a staple-like device intended to connect external tissues temporarily to aid healing. It is not absorbable.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

[53 FR 23872, June 24, 1988, as amended at 65 FR 2318, Jan. 14, 2000]

§ 878.4780 Powered suction pump.

(a) *Identification.* A powered suction pump is a portable, AC-powered or compressed air-powered device intended to be used to remove infectious materials from wounds or fluids from a patient's airway or respiratory support system. The device may be used during surgery in the operating room or at the patient's bedside. The device may include a microbial filter.

(b) *Classification.* Class II.

§ 878.4783 Negative pressure wound therapy device for reduction of wound complications.

(a) *Identification.* A negative pressure wound therapy device for reduction of wound complications is a powered suction pump intended for wound management and reduction of wound complications via application of negative pressure to the wound, which removes fluids, including wound exudate, irrigation fluids, and infectious materials. This device type is intended for use with wound dressings classified under § 878.4780. This classification does not include devices intended for organ space wounds.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical data must demonstrate that the device performs as intended under anticipated conditions of use and evaluate the following:

(i) Wound complication rates; and

(ii) All adverse events.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.

(4) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(5) Usability testing must demonstrate that intended users can correctly use the device, based solely on reading the instructions for use.

(6) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested in a worst-case scenario for the intended use life:

(i) Ability to maintain pressure levels at the wound site under a worst-case scenario for the intended use life;

(ii) Fluid removal rate consistent with the wound types specified in the indications for use; and

(iii) Timely triggering of all alarms.

(7) Performance data must demonstrate the electrical safety and electromagnetic compatibility (EMC) of the device.

(8) Software verification, validation, and hazard analysis must be performed.

(9) Labeling must include the following:

(i) Instructions for use;

(ii) A summary of the device technical specifications, including pressure settings, modes (*e.g.*, continuous or intermittent), alarms, and safety features;

(iii) Compatible components and devices;

(iv) A summary of the clinical evidence for the indications for use;

(v) A shelf life for sterile components; and

(vi) Use life and intended use environments.

(10) For devices intended for use outside of a healthcare facility, patient labeling must include the following:

(i) Information on how to operate the device and its components and the typical course of treatment;

(ii) Information on when to contact a healthcare professional; and