and specific designation numbers must be provided.

(2) Performance testing must demonstrate that the device performs as intended to mark the tissue for which it is indicated.

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

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

(5) Labeling must include:

(i) A warning that the device must not be used on a non-sterile surface prior to use internally.

(ii) An expiration date/shelf life.

(iii) Single use only labeling must be labeled directly on the device.

[80 FR 46486, Aug. 5, 2015]

§ 878.4680 Nonpowered, single patient, portable suction apparatus.

(a) *Identification.* A nonpowered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds.

(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]

§ 878.4683 Non-Powered suction apparatus device intended for negative pressure wound therapy.

(a) *Identification.* A non-powered suction apparatus device intended for negative pressure wound therapy is a device that is indicated for wound management via application of negative pressure to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials. It is further indicated for management of wounds, burns, flaps, and grafts.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT).'' See § 878.1(e) for the availability of this guidance document.

[75 FR 70114, Nov. 17, 2010]

§ 878.4685 Extracorporeal shock wave device for treatment of chronic wounds.

(a) *Identification.* An extracorporeal shock wave device for treatment of chronic wounds is a prescription device that focuses acoustic shock waves onto the dermal tissue. The shock waves are generated inside the device and transferred to the body using an acoustic interface.

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

(1) Non-clinical performance testing must be conducted to demonstrate that the system produces anticipated and reproducible acoustic pressure shock waves.

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

(3) Performance data must demonstrate that the reusable components of the device can be reprocessed for subsequent use.

(4) Performance data must be provided to demonstrate the electromagnetic compatibility and electrical safety of the device.

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

(6) Performance data must support the use life of the system by demonstrating continued system functionality over the labeled use life.

(7) Physician labeling must include:

(i) Information on how the device operates and the typical course of treatment;

(ii) A detailed summary of the device's technical parameters;

(iii) Validated methods and instructions for reprocessing of any reusable components; and

(iv) Instructions for preventing hearing loss by use of hearing protection.

(8) Patient labeling must include:

(i) Relevant contraindications, warnings, precautions, adverse effects, and complications;

(ii) Information on how the device operates and the typical course of treatment;