Subpart F—Therapeutic Devices

§ 868.5090 Emergency airway needle.

(a) *Identification.* An emergency airway needle is a device intended to puncture a patient's cricothyroid membrane to provide an emergency airway during upper airway obstruction.

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

§ 868.5095 Retrograde intubation device.

(a) *Identification.* A retrograde intubation device is a prescription device used to perform retrograde intubation via the cricothyroid membrane. The device may contain or be labeled for use with guidewires and intubating catheters, in addition to needles (§ 868.5090), syringe (§ 880.5860 of this chapter), and hemostats (§ 878.4800 of this chapter).

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

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Wire guide tensile, flex, fracture, and corrosion testing;

(ii) Catheter tensile strength testing at likely points of failure;

(iii) Catheter kink radius testing;

(iv) Compatibility of device components that interact, including compatibility in connection, disconnection, and ability to transfer fluids;

(v) Dimensional validation;

(vi) Accuracy testing of markings; and

(vii) Validation of the maximum airway pressure.

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

(3) The device must be demonstrated to be biocompatible.

(4) Labeling must include:

(i) Instructions for use; and

(ii) Package labels that clearly identify the minimum compatible size of endotracheal tube.

[86 FR 73678, Dec. 28, 2021]

§ 868.5100 Nasopharyngeal airway.

(a) *Identification.* A nasopharyngeal airway is a device used to aid breathing by means of a tube inserted into a patient's pharynx through the nose to provide a patent airway.

(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 the limitations in § 868.9.

[47 FR 31142, July 16, 1982, as amended at 61 FR 1120, Jan. 16, 1996; 66 FR 38794, July 25, 2001]

§ 868.5105 External negative pressure airway aid.

(a) *Identification.* An external negative pressure airway aid is a prescription device that applies negative pressure to a patient's neck to aid in providing a patent airway during procedures requiring anesthesia.

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

(1) Clinical performance testing must document any adverse events observed during clinical use, including impaired blood flow, and demonstrate that the device performs as intended under anticipated conditions.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated patient positions, does not fail during use, and does not lose negative pressure capability. The following testing should be performed:

(i) Ability of the device to maintain a seal during various patient positions;

(ii) Device leakage testing to demonstrate the device maintains vacuum;

(iii) Drop testing to ensure the device does not incur functional damage after dropping the device; and

(iv) Functional testing after high and low storage temperature.

(3) All patient contacting components must be demonstrated to be biocompatible.

(4) Labeling must include:

(i) A summary of clinical testing results, including any adverse events and evidence that effectiveness has been achieved.