Food and Drug Administration, HHS

§ 868.5180 Rocking bed.
(a) Identification. A rocking bed is a device intended for temporary use to help patient ventilation (breathing) by repeatedly tilting the patient, thereby using the weight of the abdominal contents to move the diaphragm.

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

§ 868.5220 Blow bottle.
(a) Identification. A blow bottle is a device that is intended for medical purposes to induce a forced expiration from a patient. The patient blows into the device to move a column of water from one bottle to another.

(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. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing system regulation in part 820 of this chapter with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 868.5240 Anesthesia breathing circuit.
(a) Identification. An anesthesia breathing circuit is a device that is intended to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.

(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.