§ 868.2480 Cutaneous carbon dioxide (PcCO₂) monitor.

(a) Identification. A cutaneous carbon dioxide (PcCO₂) monitor is a noninvasive heated sensor and a pH-sensitive glass electrode placed on a patient’s skin, which is intended to monitor relative changes in a hemodynamically stable patient’s cutaneous carbon dioxide tension as an adjunct to arterial carbon dioxide tension measurement.

(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO₂) and Oxygen (PcO₂) Monitors; Guidance for Industry and FDA.” See §868.1(e) for the availability of this guidance document.

§ 868.2620 Gas pressure calibrator.

(a) Identification. A gas pressure calibrator is a device intended for medical purposes that is used to calibrate pressure-measuring instruments by generating a known gas pressure.

(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.