Food and Drug Administration, HHS

§ 868.1430 Carbon monoxide gas analyzer.

(a) Identification. A carbon monoxide gas analyzer is a device intended to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient’s ventilatory status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, or mass spectrometry.

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

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§ 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.

(a) Identification. An indwelling blood hydrogen ion concentration (pH) analyzer is a device that consists of a catheter-tip pH electrode and that is used to measure, in vivo, the hydrogen ion concentration (pH) in blood to aid in determining the patient’s acid-base balance.

(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA.”


§ 868.1200 Indwelling blood oxygen partial pressure (PO₂) analyzer.

(a) Identification. An indwelling blood oxygen partial pressure (PO₂) analyzer is a device that consists of a catheter-tip PO₂ transducer (e.g., PO₂ electrode) and that is used to measure, in vivo, the partial pressure of oxygen in blood to aid in determining the patient’s circulatory, ventilatory, and metabolic status.

(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA.”


§ 868.1150 Indwelling blood carbon dioxide partial pressure (PCO₂) analyzer.

(a) Identification. An indwelling blood carbon dioxide partial pressure (PCO₂) analyzer is a device that consists of a catheter-tip PCO₂ transducer (e.g., PCO₂ electrode) and that is used to measure, in vivo, the partial pressure of carbon dioxide in blood to aid in determining the patient’s circulatory, ventilatory, and metabolic status.

(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Indwelling Blood Gas Analyzers; Final Guidance for Industry and FDA.”


§ 868.1400 Carbon dioxide gas analyzer.

(a) Identification. A carbon dioxide gas analyzer is a device intended to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient’s ventilatory, circulatory, and metabolic status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, or mass spectrometry.

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

§ 868.1430 Carbon monoxide gas analyzer.

(a) Identification. A carbon monoxide gas analyzer is a device intended to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient’s ventilatory status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, or mass spectrometry.

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