§ 866.6020 Immunomagnetic circulating cancer cell selection and enumeration system.

(a) Identification. An immunomagnetic circulating cancer cell selection and enumeration system is a device that consists of biological probes, fluorochromes, and other reagents; preservation and preparation devices; and a semiautomated analytical instrument to select and count circulating cancer cells in a prepared sample of whole blood. This device is intended for adjunctive use in monitoring or predicting cancer disease progression, response to therapy, and for the detection of recurrent disease.

(b) Classification. Class II (special controls). The special control for this device is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System.” See §866.1(e) for availability of this guidance document.

[69 FR 26291, May 9, 2007]

PART 868—ANESTHESIOLOGY DEVICES

Subpart A—General Provisions

Sec. 868.1 Scope.
868.3 Effective dates of requirement for premarket approval.
868.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

868.1030 Manual algesimeter.
868.1040 Powered algesimeter.
868.1075 Argon gas analyzer.
868.1100 Arterial blood sampling kit.
868.1150 Indwelling blood carbon dioxide partial pressure (P_{CO2}) analyzer.
868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.
868.1200 Indwelling blood oxygen partial pressure (P_{O2}) analyzer.
868.1250 Enflurane gas analyzer.
868.1270 Gas collection vessel.
868.1290 Halothane gas analyzer.
868.1540 Neon gas analyzer.
868.1560 Helium gas analyzer.
868.1570 Gas collection vessel.