

§ 866.6010

Quality Control Material for Cystic Fibrosis Nucleic Acid Assays.” See § 866.1(e) for the availability of this guidance document.

[72 FR 1176, Jan. 10, 2007]

Subpart G—Tumor Associated Antigen Immunological Test Systems

§ 866.6010 Tumor-associated antigen immunological test system.

(a) *Identification.* A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

(b) *Classification.* Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled “Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)s) to FDA,” and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.

[62 FR 66005, Dec. 17, 1997]

§ 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 Cir-

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culating Cancer Cell Selection and Enumeration System.” See § 866.1(e) for availability of this guidance document.

[69 FR 26038, May 11, 2004]

§ 866.6030 AFP-L3% immunological test system.

(a) *Identification.* An AFP-L3% immunological test system is an in vitro device that consists of reagents and an automated instrument used to quantitatively measure, by immunochemical techniques, AFP and AFP-L3 subfraction in human serum. The device is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma, in conjunction with other laboratory findings, imaging studies, and clinical assessment.

(b) *Classification.* Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems.” See § 866.1(e) for the availability of this guidance document.

[70 FR 57749, Oct. 4, 2005]

§ 866.6040 Gene expression profiling test system for breast cancer prognosis.

(a) *Identification.* A gene expression profiling test system for breast cancer prognosis is a device that measures the ribonucleic acid (RNA) expression level of multiple genes and combines this information to yield a signature (pattern or classifier or index) to aid in prognosis of previously diagnosed breast cancer.

(b) *Classification.* Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis.” See § 866.1(e) for the availability of this guidance document.

[72 FR 26291, May 9, 2007]

§ 866.6050 Ovarian adnexal mass assessment score test system.

(a) *Identification.* An ovarian/adnexal mass assessment test system is a device that measures one or more proteins in serum or plasma. It yields a

single result for the likelihood that an adnexal pelvic mass in a woman, for whom surgery is planned, is malignant. The test is for adjunctive use, in the context of a negative primary clinical and radiological evaluation, to augment the identification of patients whose gynecologic surgery requires oncology expertise and resources.

(b) *Classification*. Class II (special controls). The special control for this device is FDA’s guidance document entitled “Class II Special Controls Guid-

ance Document: Ovarian Adnexal Mass Assessment Score Test System.” For the availability of this guidance document, see §866.1(e).

(c) *Black box warning*. Under section 520(e) of the Federal Food, Drug, and Cosmetic Act these devices are subject to the following restriction: A warning statement must be placed in a black box and must appear in all advertising, labeling, and promotional material for these devices. That warning statement must read:

PRECAUTION: The [test name] should not be used without an independent clinical/radiological evaluation and is **not** intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of the [test name] carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.

[76 FR 16294, Mar. 23, 2011, as amended at 76 FR 82131, Dec. 30, 2011]

PART 868—ANESTHESIOLOGY DEVICES

Subpart A—General Provisions

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- 868.1 Scope.
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- 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 algometer.
- 868.1040 Powered algometer.
- 868.1075 Argon gas analyzer.
- 868.1100 Arterial blood sampling kit.
- 868.1120 Indwelling blood oxyhemoglobin concentration analyzer.
- 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.
- 868.1400 Carbon dioxide gas analyzer.
- 868.1430 Carbon monoxide gas analyzer.
- 868.1500 Enflurane gas analyzer.
- 868.1575 Gas collection vessel.

- 868.1620 Halothane gas analyzer.
- 868.1640 Helium gas analyzer.
- 868.1670 Neon gas analyzer.
- 868.1690 Nitrogen gas analyzer.
- 868.1700 Nitrous oxide gas analyzer.
- 868.1720 Oxygen gas analyzer.
- 868.1730 Oxygen uptake computer.
- 868.1750 Pressure plethysmograph.
- 868.1760 Volume plethysmograph.
- 868.1780 Inspiratory airway pressure meter.
- 868.1800 Rhinomanometer.
- 868.1840 Diagnostic spirometer.
- 868.1850 Monitoring spirometer.
- 868.1860 Peak-flow meter for spirometry.
- 868.1870 Gas volume calibrator.
- 868.1880 Pulmonary-function data calculator.
- 868.1890 Predictive pulmonary-function value calculator.
- 868.1900 Diagnostic pulmonary-function interpretation calculator.
- 868.1910 Esophageal stethoscope.
- 868.1920 Esophageal stethoscope with electrical conductors.
- 868.1930 Stethoscope head.
- 868.1965 Switching valve (ploss).
- 868.1975 Water vapor analyzer.

Subpart C—Monitoring Devices

- 868.2025 Ultrasonic air embolism monitor.
- 868.2300 Bourdon gauge flowmeter.
- 868.2320 Uncompensated thorpe tube flowmeter.