

§ 876.1075

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2316, Jan. 14, 2000]

Subpart B—Diagnostic Devices

§ 876.1075 Gastroenterology-urology biopsy instrument.

(a) *Identification.* A gastroenterology-urology biopsy instrument is a device used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination. This generic type of device includes the biopsy punch, gastrointestinal mechanical biopsy instrument, suction biopsy instrument, gastro-urology biopsy needle and needle set, and nonelectric biopsy forceps. This section does not apply to biopsy instruments that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the biopsy forceps cover and the non-electric biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in sub-

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part E of part 807 of this chapter subject to the limitations in § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001]

§ 876.1300 Ingestible telemetric gastrointestinal capsule imaging system.

(a) *Identification.* An ingestible telemetric gastrointestinal capsule imaging system is used for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel. The device captures images of the small bowel with a wireless camera contained in a capsule. This device includes an ingestible capsule (containing a light source, camera, transmitter, and battery), an antenna array, a receiving/recording unit, a data storage device, computer software to process the images, and accessories.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance, "Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging Systems; Final Guidance for Industry and FDA."

[67 FR 3433, Jan. 24, 2002]

§ 876.1400 Stomach pH electrode.

(a) *Identification.* A stomach pH electrode is a device used to measure intragastric and intraesophageal pH (hydrogen ion concentration). The pH electrode is at the end of a flexible lead which may be inserted into the esophagus or stomach through the patient's mouth. The device may include an integral gastrointestinal tube.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996]

§ 876.1500 Endoscope and accessories.

(a) *Identification.* An endoscope and accessories is a device used to provide access, illumination, and allow observation or manipulation of body cavities, hollow organs, and canals. The device consists of various rigid or flexible instruments that are inserted into body spaces and may include an optical system for conveying an image to the