(3) The clinical performance characteristics of the device for the detection of colon polyps must be established. Demonstration of the performance characteristics must include assessment of positive percent agreement and negative percent agreement compared to a clinically acceptable alternative structural imaging method.

(4) Clinician labeling must include:

(i) Specific instructions and the clinical and technical expertise needed for the safe use of the device.

(ii) A detailed summary of the clinical testing pertinent to use of the device, including the percentage of patients in which a polyp was correctly identified by capsule endoscopy, but also the percent of patients in which the capsule either missed or falsely identified a polyp with respect to the clinically acceptable alternative structural imaging method.

(iii) The colon cleansing procedure.

(iv) A detailed summary of the device technical parameters.

(v) A detailed summary of the device- and procedure-related complications pertinent to use of the device.

(vi) An expiration date/shelf life.

(5) Patient labeling must include:

(i) An explanation of the device and the mechanism of operation.

(ii) Patient preparation procedure.

(iii) A brief summary of the clinical study. The summary should not only include the percentage of patients in which a polyp was correctly identified by capsule endoscopy, but also the percent of patients in which the capsule either missed or falsely identified a polyp with respect to the clinically acceptable alternative structural imaging method.

(iv) A summary of the device- and procedure-related complications pertinent to use of the device.

[79 FR 28403, May 16, 2014]

§ 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]

§ 876.1450 Esophageal tissue characterization system.

(a) *Identification.* An esophageal tissue characterization system is a device intended for obtaining measurements of electrical properties within esophageal tissue.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) All patient contacting components of the device must be demonstrated to be biocompatible.

(2) Performance testing must demonstrate the device can accurately measure the designated electrical characteristics.

(3) Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Electromagnetic compatibility and electrical safety, mechanical safety, and thermal safety of the device must be performed.

(6) Performance data must validate the reprocessing instructions for any reusable components of the device.

(7) Labeling must include:

(i) Specific instructions regarding the proper placement and use of the device;

(ii) Instructions for reprocessing of any reusable components; and

(iii) An expiration date for single use components.

[86 FR 68399, Dec. 2, 2021]

§ 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 user's eye and their accessories may assist in gaining access or increase the

versatility and augment the capabilities of the devices. Examples of devices that are within this generic type of device include cleaning accessories for endoscopes, photographic accessories for endoscopes, nonpowered anoscopes, binolcular attachments for endoscopes, pocket battery boxes, flexible or rigid choledochoscopes, colonoscopes, diagnostic cystoscopes, cystourethroscopes, enteroscopes, esophagogastroduodenoscopes, rigid esophagoscopes, fiberoptic illuminators for endoscopes, incandescent endoscope lamps, biliary pancreatoscopes, proctoscopes, resectoscopes, nephroscopes, sigmoidoscopes, ureteroscopes, urethroscopes, endomagnetic retrievers, cytology brushes for endoscopes, and lubricating jelly for transurethral surgical instruments. This section does not apply to endoscopes 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 (special controls)*. The device, when it is an endoscope disinfectant basin, which consists solely of a container that holds disinfectant and endoscopes and accessories; an endoscopic magnetic retriever intended for single use; sterile scissors for cystoscope intended for single use; a disposable, non-powered endoscopic grasping/cutting instrument intended for single use; a diagnostic incandescent light source; a fiberoptic photographic light source; a routine fiberoptic light source; an endoscopic sponge carrier; a xenon arc endoscope light source; an endoscope transformer; an LED light source; or a gastroenterology-urology endoscopic guidewire, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

(2) Class I for the photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807of 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; 83 FR 25914, June 5, 2018; 84 FR 71813, Dec. 30, 2019]

§ 876.1520 Gastrointestinal lesion software detection system.

(a) *Identification*. A gastrointestinal lesion software detection system is a computer-assisted detection device used in conjunction with endoscopy for the detection of abnormal lesions in the gastrointestinal tract. This device with advanced software algorithms brings attention to images to aid in the detection of lesions. The device may contain hardware to support interfacing with an endoscope.

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including detection of gastrointestinal lesions and evaluation of all adverse events.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:

(i) Standalone algorithm performance testing;

(ii) Pixel-level comparison of degradation of image quality due to the device;

(iii) Assessment of video delay due to marker annotation; and

(iv) Assessment of real-time endoscopic video delay due to the device.

(3) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.

(4) Performance data must demonstrate electromagnetic compatibility and electrical safety, mechanical safety, and thermal safety testing for any hardware components of the device.