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

(5) Software verification, validation, and hazard analysis must be provided. Software description must include a detailed, technical description including the impact of any software and hardware on the device's functions, the associated capabilities and limitations of each part, the associated inputs and outputs, mapping of the software architecture, and a description of the video signal pipeline.

(6) Labeling must include:

(i) Instructions for use, including a detailed description of the device and compatibility information;

(ii) Warnings to avoid overreliance on the device, that the device is not intended to be used for diagnosis or characterization of lesions, and that the device does not replace clinical decision making;

(iii) A summary of the clinical performance testing conducted with the device, including detailed definitions of the study endpoints and statistical confidence intervals; and

(iv) A summary of the standalone performance testing and associated statistical analysis.

[88 FR 10, Jan. 3, 2023]

§ 876.1620 Urodynamics measurement system.

(a) *Identification.* A urodynamics measurement system is a device used to measure volume and pressure in the urinary bladder when it is filled through a catheter with carbon dioxide or water. The device controls the supply of carbon dioxide or water and may also record the electrical activity of the muscles associated with urination. The device system may include transducers, electronic signal conditioning and display equipment, a catheter withdrawal device to enable a urethral pressure profile to be obtained, and special catheters for urethral profilometry and electrodes for electromyography. This generic type of device includes the cystometric gas (carbon dioxide) device, the cystometric hydrualic device, and the electrical recording cystometer, but excludes any device that uses air to fill the bladder.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998]

§ 876.1725 Gastrointestinal motility monitoring system.

(a) *Identification.* A gastrointestinal motility monitoring system is a device used to measure peristalic activity or pressure in the stomach or esophagus by means of a probe with transducers that is introduced through the mouth into the gastrointestinal tract. The device may include signal conditioning, amplifying, and recording equipment. This generic type of device includes the esophageal motility monitor and tube, the gastrointestinal motility (electrical) system, and certain accessories, such as a pressure transducer, amplifier, and external recorder.

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

§ 876.1735 Electrogastrography system.

(a) *Identification.* An electrogastrography system (EGG) is a device used to measure gastric myoelectrical activity as an aid in the diagnosis of gastric motility disorders. The device system includes the external recorder, amplifier, skin electrodes, strip chart, cables, analytical software, and other accessories.

(b) *Classification.* Class II (Special Controls). The special controls are as follows:

(1) The sale, distribution and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter.

(2) The labeling must include specific instructions:

(i) To describe proper patient set-up prior to the start of the test, including the proper placement of electrodes;

(ii) To describe how background data should be gathered and used to eliminate artifact in the data signal;

(iii) To describe the test protocol (including the measurement of baseline

data) that may be followed to obtain the EGG signal; and

(iv) To explain how data results may be interpreted.

(3) The device design should ensure that the EGG signal is distinguishable from background noise that may interfere with the true gastric myoelectric signal.

(4) Data should be collected to demonstrate that the device has adequate precision and the EGG signal is reproducible and is interpretable.

[64 FR 51444, Sept. 23, 1999]

§ 876.1800 Urine flow or volume measuring system.

(a) *Identification.* A urine flow or volume measuring system is a device that measures directly or indirectly the volume or flow of urine from a patient, either during the course of normal urination or while the patient is catheterized. The device may include a drip chamber to reduce the risk of retrograde bacterial contamination of the bladder and a transducer and electrical signal conditioning and display equipment. This generic type of device includes the electrical urinometer, mechanical urinometer, nonelectric urinometer, disposable nonelectric urine flow rate measuring device, and uroflowmeter.

(b) *Classification.* (1) Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 61 FR 1122, Jan. 16, 1996; 63 FR 59228, Nov. 3, 1998]

Subpart C—Monitoring Devices

§ 876.2040 Enuresis alarm.

(a) *Identification.* An enuresis alarm is a device intended for use in treatment of bedwetting. Through an electrical trigger mechanism, the device sounds an alarm when a small quantity of urine is detected on a sensing pad. This generic type of device includes conditioned response enuresis alarms.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9.

[48 FR 53023, Nov. 23, 1983, as amended at 63 FR 59228, Nov. 3, 1998]

§ 876.2050 Prostate lesion documentation system.

(a) *Identification.* A prostate lesion documentation system is a prescription device intended for use in producing an image of the prostate as an aid in documenting prostate abnormalities previously identified during a digital rectal examination. The device uses pressure sensors and image reconstruction software to produce a prostate image that highlights regional differences in intraprostatic tissue elasticity or stiffness. The device is limited to use as a documentation tool and is not intended for diagnostic purposes or for influencing any clinical decisions.

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

(1) Non-clinical and clinical performance testing must demonstrate the accuracy and reproducibility of the constructed image.

(2) Appropriate analysis/testing must validate electromagnetic compatibility, electrical safety, thermal safety, and mechanical safety.

(3) Appropriate software verification, validation, and hazard analysis must be performed.

(4) All elements of the device that may contact the patient must be demonstrated to be biocompatible.

(5) Methods and instructions for reprocessing of any reusable components must be properly validated.

(6) The labeling must include specific information needed to ensure proper use of the device.

[80 FR 72900, Nov. 23, 2015]

§ 876.2100 Pressure ulcer management tool.

(a) *Identification.* A pressure ulcer management tool is a prescription device intended for patients at risk of developing pressure ulcers. The device provides output that supports a user's decision to increase intervention. The device is an adjunct tool for pressure ulcer management that is not intended for detection or diagnostic purposes.