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

(2) Performance data must demonstrate the sterility of patient-contacting components of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the requested shelf life.

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Dimensional verification testing must be conducted.

(ii) Force verification testing must be conducted. The force testing must demonstrate the forces necessary to insert and operate each component of the device during use as intended.

(iii) Functional verification testing of the device components must be conducted.

(5) Simulated use testing in an anatomically relevant animal model must demonstrate the device's ability to penetrate soft tissue, be assembled in situ, and to grasp, hold and manipulate soft tissues in the intended treatment area.

(6) The labeling must include the following:

(i) Instructions for use, including detailed instructions for instrument assembly, disassembly, and removal; and

(ii) A shelf life.

[86 FR 71569, Dec. 17, 2021]

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

(a) *Identification.* (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide.

(2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

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

(2) Class I for special laser gas mixtures used as a lasing medium for this class of lasers. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38803, July 25, 2001]

§ 878.4815 Magnetic surgical instrument system.

(a) *Identification.* A magnetic surgical instrument system is a prescription device used in laparoscopic surgical procedures consisting of several components, such as surgical instruments, and a magnetic controller. The magnetic controller is provided separately from the surgical instrument and is used outside the patient. The external magnetic controller is magnetically coupled with the internal surgical instrument(s) at the surgical site to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.

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

(1) In vivo performance data must demonstrate that the device performs as intended under anticipated conditions of use. Testing must demonstrate the ability of the device to grasp, hold, retract, mobilize, or manipulate soft tissue and organs.

(2) Non-clinical performance data must demonstrate that the system performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Magnetic field strength testing characterization to identify the distances from the magnet that are safe for patients and users with ferromagnetic implants, devices, or objects.

(ii) Ability of the internal surgical instrument(s) to be coupled, de-coupled, and re-coupled with the external magnet over the external magnet use life.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of the device components that are patient-contacting.

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