(iii) The probable risks and benefits associated with the use of the device;

(iv) Post-procedure care instructions; and

(v) Alternative treatments.

[83 FR 9699, Mar. 7, 2018]

§ 878.4700 Surgical microscope and accessories.

(a) *Identification.* A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

(a) *Identification.* A surgical skin degreaser or an adhesive tape solvent is a device that consists of a liquid such as 1,1,2-trichloro-1,2,2-trifluoroethane; 1,1,1-trichloroethane; and 1,1,1-trichloroethane with mineral spirits intended to be used to dissolve surface skin oil or adhesive tape.

(b) *Classification.* Class I (general controls). The device is 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 59 FR 63010, Dec. 7, 1994; 66 FR 38803, July 25, 2001]

§ 878.4740 Surgical stapler.

(a) Surgical stapler for external use.

(1) *Identification.* A surgical stapler for external use is a specialized prescription device used to deliver compatible staples to skin during surgery.

(2) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.

(b) Surgical stapler for internal use.

(1) *Identification.* A surgical stapler for internal use is a specialized prescription device used to deliver compatible staples to internal tissues during surgery for resection, transection, and creating anastomoses.

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

(i) Performance testing must demonstrate that the stapler, when used with compatible staples, performs as intended under anticipated conditions of use. Performance testing must include the following:

(A) Evaluation of staple formation characteristics in the maximum and minimum tissue thicknesses for each staple type;

(B) For manual staplers only, measurement of the worst-case deployment pressures on stapler firing force;

(C) Measurement of staple line strength;

(D) Confirmation of staple line integrity; and

(E) In vivo confirmation of staple line hemostasis.

(ii) For powered staplers only, appropriate analysis/testing must demonstrate the electromagnetic compatibility and electrical, thermal, and mechanical safety of the device.

(iii) For powered staplers only, appropriate software verification, validation, and hazard analysis must be performed.

(iv) Human factors testing must demonstrate that the clinician can correctly select and safely use the device, as identified in the labeling, based on reading the directions for use.

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

(vi) Performance data must demonstrate the sterility of the device.

(vii) Validation of cleaning and sterilization instructions must demonstrate that any reusable device components can be safely and effectively reprocessed per the recommended cleaning and sterilization protocol in the labeling.

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

(ix) Labeling of the device must include the following:

(A) Unless data demonstrates the safety of doing so, contraindications