The use of laparoscopic power morcellators may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk;''

(iv) A statement limiting use of device to physicians who have completed the training program; and

(v) A shelf life.

[86 FR 66458, Nov. 23, 2021]

§ 878.4830 Absorbable surgical gut suture.

(a) *Identification.* An absorbable surgical gut suture, both plain and chromic, is an absorbable, sterile, flexible thread prepared from either the serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine, and is intended for use in soft tissue approximation.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

[54 FR 50738, Dec. 11, 1989, as amended at 68 FR 32984, June 3, 2003]

§ 878.4840 Absorbable polydioxanone surgical suture.

(a) *Identification.* An absorbable polydioxanone surgical suture is an absorbable, flexible, sterile, monofilament thread prepared from polyester polymer poly (p-dioxanone) and is intended for use in soft tissue approximation, including pediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. It may be coated or uncoated, undyed or dyed, and with or without a standard needle attached.

(b) *Classification.* Class II (special controls). The special control for the device is FDA's ''Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA.'' See § 878.1(e) for the availability of this guidance document.

[67 FR 77676, Dec. 19, 2002]

§ 878.4850 Blood lancets.

(a) *Single use only blood lancet with an integral sharps injury prevention feature*—(1) *Identification.* A disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base (including an integral sharps injury prevention feature) that is used to puncture the skin to obtain a drop of blood for diagnostic purposes. The integral sharps injury prevention feature allows the device to be used once and then renders it inoperable and incapable of further use.

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

(i) The design characteristics of the device must ensure that the structure and material composition are consistent with the intended use and must include a sharps injury prevention feature.

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use and that the integral sharps injury prevention feature will irreversibly disable the device after one use.

(iii) The device must be demonstrated to be biocompatible.

(iv) Sterility testing must demonstrate the sterility of any device component that breaches the skin (*e.g.*, blade).

(v) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device and its sharps injury prevention feature.

(B) Handwashing instructions for the user before and after use of the device.

(C) Instructions on preparation (*e.g.*, cleaning, disinfection) of the skin to be pierced.

(D) Instructions for the safe disposal of the device.

(E) Labeling must be appropriate for the intended use environment.

(*1*) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(*2*) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed: