§ 878.4370  
A cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold. The device is intended to treat disease conditions such as tumors, skin cancers, acne scars, or hemangiomas (benign tumors consisting of newly formed blood vessels) and various benign or malignant gynecological conditions affecting vulvar, vaginal, or cervical tissue. The device is not intended for urological applications.

(b) Classification. Class II.

§ 878.4380  
A drape adhesive is a device intended to be placed on the skin to attach a surgical drape.

(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.

§ 878.4400  
An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.

(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.

§ 878.4410  
A low energy ultrasound wound cleaner is a device that uses ultrasound energy to vaporize a solution and generate a mist that is used for the cleaning and maintenance debridement of wounds. Low levels of ultrasound energy may be carried to the wound by the saline mist.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Low Energy Ultrasound Wound Cleaner.” See §878.1(e) for the availability of this guidance document.

(b) Classification. Class II.

§ 878.4440  
An eye pad is a device that consists of a pad made of various materials, such as gauze and cotton, intended for use as a bandage over the eye for protection or absorption of secretions.

(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.

§ 878.4450  
Nonabsorbable gauze for internal use is a device made of an open mesh fabric intended to be used inside the body or a surgical incision or applied to internal organs or structures, to control bleeding, absorb fluid, or protect organs or structures from abrasion, drying, or contamination. The device is woven from material made of not less than 50 percent by mass cotton, cellulose, or a simple chemical derivative of cellulose, and contains x-ray detectable elements.

(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.