life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in §812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2317, Jan. 14, 2000]

Subpart B—Diagnostic Devices

§ 878.1800 Speculum and accessories.

(a) Identification. A speculum is a device intended to be inserted into a body cavity to aid observation. It is either nonilluminated or illuminated and may have various accessories.

(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 §878.9.


Subpart D—Prosthetic Devices

§ 878.3250 External facial fracture fixation appliance.

(a) Identification. An external facial fracture fixation appliance is a metal apparatus intended to be used during surgical reconstruction and repair to immobilize maxillofacial bone fragments in their proper facial relationship.

(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 §878.9.
May 28, 1976. Any other silicone inflatable breast prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[53 FR 23872, June 24, 1988, as amended at 64 FR 45161, Aug. 19, 1999]

§ 878.3540 Silicone gel-filled breast prosthesis.

(a) Identification—(1) Single-lumen silicone gel-filled breast prosthesis. A single-lumen silicone gel-filled breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The shell either contains a fixed amount cross-linked polymerized silicone gel, fillers, and stabilizers or is filled to the desired size with injectable silicone gel at time of implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(2) Double-lumen silicone gel-filled breast prosthesis. A double lumen silicone gel-filled breast prosthesis is a silicone rubber inner shell and a silicone rubber outer shell, both shells made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The inner shell contains fixed amounts of cross-linked polymerized silicone gel, fillers, and stabilizers. The outer shell is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(3) Polyurethane covered silicone gel-filled breast prosthesis. A polyurethane covered silicone gel-filled breast prosthesis is an inner silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, with an outer silicone adhesive layer and an outer covering of polyurethane; contained within the inner shell is a fixed amount of cross-linked polymerized silicone gel, fillers, and stabilizers and an inert support structure compartmentalizing the silicone gel. The device is intended to be implanted to augment or reconstruct the female breast.

(b) Classification. Class III.

c. Date premarket approval application (PMA) is required. A PMA is required to be filed with the Food and Drug Administration on or before July 9, 1991 for any silicone gel-filled breast prosthesis that was in commercial distribution before May 28, 1976, or that has on or before July 9, 1991 been found to be substantially equivalent to a silicone gel-filled breast prosthesis that was in commercial distribution before May 28, 1976. Any other silicone gel-filled breast prosthesis shall have an approved PMA in effect before being placed in commercial distribution.

[53 FR 23872, June 24, 1988, as amended at 56 FR 14627, Apr. 10, 1991]

§ 878.3550 Chin prosthesis.

(a) Identification. A chin prosthesis is a silicone rubber solid device intended to be implanted to augment or reconstruct the chin.

(b) Classification. Class II.

§ 878.3590 Ear prosthesis.

(a) Identification. An ear prosthesis is a silicone rubber solid device intended to be implanted to reconstruct the external ear.

(b) Classification. Class II.

§ 878.3610 Esophageal prosthesis.

(a) Identification. An esophageal prosthesis is a rigid, flexible, or expandable tubular device made of a plastic, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the esophagus. The metal esophageal prosthesis may be uncovered or covered with a polymeric material. This device may also include a device delivery system.

(b) Classification. Class II. The special control for this device is FDA’s “Guidance for the Content of Premarket Notification Submissions for Esophageal and Tracheal Prostheses.”

[65 FR 17145, Mar. 31, 2000]

§ 878.3680 Nose prosthesis.

(a) Identification. A nose prosthesis is a silicone rubber solid device intended to be implanted to augment or reconstruct the nasal dorsum.

(b) Classification. Class II.

§ 878.3720 Tracheal prosthesis.

(a) Identification. The tracheal prosthesis is a rigid, flexible, or expandable
§ 878.3750 External prosthesis adhesive.

(a) Identification. An external prosthesis adhesive is a silicone-type adhesive intended to be used to fasten to the body an external aesthetic restoration prosthesis, such as an artificial nose.

(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 §878.9.

§ 878.3800 External aesthetic restoration prosthesis.

(a) Identification. An external aesthetic restoration prosthesis is a device intended to be used to reconstruct an external artificial body structure, such as an ear, breast, or nose. Usually the device is made of silicone rubber and it may be fastened to the body with an external prosthesis adhesive. The device is not intended to be implanted.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, with the exception of §820.180 of this chapter, with respect to records, and §820.198 of this chapter, with respect to complaint files.

§ 878.3900 Inflatable extremity splint.

(a) Identification. An inflatable extremity splint is a device intended to be inflated to immobilize a limb or an extremity.

(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.

§ 878.3910 Noninflatable extremity splint.

(a) Identification. A noninflatable extremity splint is a device intended to immobilize a limb or an extremity. It is not inflatable.

(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 §878.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180 of this chapter, with respect to records, and §820.198 of this chapter, with respect to complaint files.

§ 878.3925 Plastic surgery kit and accessories.

(a) Identification. A plastic surgery kit and accessories is a device intended to be used to reconstruct maxillofacial deficiencies. The kit contains surgical instruments and materials used to make maxillofacial impressions before molding an external prosthesis.

(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 §878.9.


Subpart E—Surgical Devices

§ 878.4010 Tissue adhesive.

(a) Identification. A tissue adhesive for the topical approximation of skin—

(1) Identification. A tissue adhesive for the topical approximation of skin is a device intended for topical closure of surgical incisions, including laparoscopic incisions, and simple traumatic lacerations that have easily approximated skin edges. Tissue adhesives for the topical approximation of skin may be used in conjunction with, but not in place of, deep dermal stitches.

(2) Classification. Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin." See §878.1(e) of this chapter for the availability of this guidance document.

(b) Tissue adhesive for non-topical use—(1) Identification. A tissue adhesive for non-topical use, including adhesives intended for use in the embolization of brain arteriovenous malformation or for use in ophthalmic surgery, is a device used for the adhesion of internal tissues and vessels.

(2) Classification. Class III (premarket approval). As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See §878.3 of this chapter.

[73 FR 31033, May 30, 2008]

§ 878.4011 Tissue adhesive with adjunct wound closure device for topical approximation of skin.

(a) Identification. A tissue adhesive with adjunct wound closure device intended for the topical approximation of skin is a device indicated for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. It may be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of wound during application of the liquid adhesive.

(b) Classification. Class II (special controls). The special control for this device is FDA's "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin." See §878.1(e) for the availability of this guidance document.

[75 FR 68794, Nov. 10, 2010]

§ 878.4014 Nonresorbable gauze/sponge for external use.

(a) Identification. A nonresorbable gauze/sponge for external use is a sterile or nonsterile device intended for medical purposes, such as to be placed directly on a patient’s wound to absorb exudate. It consists of a strip, piece, or pad made from open woven or nonwoven mesh cotton cellulose or a simple chemical derivative of cellulose. This classification does not include a nonresorbable gauze/sponge for external use that contains added drugs such as antimicrobial agents, added biologics such as growth factors, or is composed of materials derived from animal sources.

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

[64 FR 53929, Oct. 5, 1999]

§ 878.4015 Wound dressing with poly(diallyl dimethyl ammonium chloride) (pDADMAC) additive.

(a) Identification. A wound dressing with pDADMAC additive is intended for use as a primary dressing for exuding wounds, 1st and 2nd degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

(b) Classification. Class II (special controls). The special control is: the FDA guidance document entitled "Class II Special Controls Guidance Document: Wound Dressing With Poly