

§ 878.1800

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring 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 the limitations in § 878.9.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13827, Apr. 5, 1989; 59 FR 63010, Dec. 7, 1994; 66 FR 38802, July 25, 2001]

Subpart C [Reserved]

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

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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.

[53 FR 23872, June 24, 1988, as amended at 54 FR 13827, Apr. 5, 1989; 65 FR 2317, Jan. 14, 2000]

§ 878.3300 Surgical mesh.

(a) *Identification.* Surgical mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists. Examples of surgical mesh are metallic and polymeric mesh for hernia repair, and acetabular and cement restrictor mesh used during orthopedic surgery.

(b) *Classification.* Class II.

§ 878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.

(a) *Identification.* A polytetrafluoroethylene with carbon fibers composite implant material is a porous device material intended to be implanted during surgery of the chin, jaw, nose, or bones or tissue near the eye or ear. The device material serves as a space-occupying substance and is shaped and formed by the surgeon to conform to the patient's need.

(b) *Classification.* Class II.

§ 878.3530 Silicone inflatable breast prosthesis.

(a) *Identification.* A silicone inflatable breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, that 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.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 17, 1999, for any silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976, or that has, on