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 tubular device made of a silicone, metal, or polymeric material that is intended to be implanted to restore the structure and/or function of the trachea or trachealbronchial tree. It may be unbranched or contain one or two branches. The metal tracheal 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 17146, Mar. 31, 2000]

§ 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 the limitations in § 878.9.

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

§ 878.3800 External aesthetic restoration prosthesis.

(a) *Identification*. An external aesthetic restoration prosthesis is a device intended to be used to construct 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