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 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.

§ 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.