

PRESENT CFR LISTING for ABSORBABLE HEMOSTATIC AGENT and DRESSING

- (a) *Identification.* An absorbable hemostatic agent or dressing is a device intended to produce hemostasis by accelerating the clotting process of blood. It is absorbable
- (b) *Classification.* Class III.
- (c) *Date PMA or notice of completion of a PDP is required.* 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.

PROPOSED IDENTIFICATION for THE ABSORBABLE HEMOSTATIC AGENT and DRESSING

- (a) *Identification.* An absorbable hemostatic agent or dressing is a device intended to produce hemostasis by accelerating the clotting process of blood. It is absorbable.
- (b) *Classification.* Class II for those without bovine thrombin. Class III for those containing bovine thrombin.
- (c) *Date PMA or notice of completion of a PDP is required.* 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.