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TITLE 21--FOOD AND DRUGS
 CHAPTER I--FOOD AND DRUG ADMINISTRATION
 DEPARTMENT OF HEALTH AND HUMAN SERVICES
 SUBCHAPTER H--MEDICAL DEVICES

[PART 878 -- GENERAL AND PLASTIC SURGERY DEVICES](#)

Subpart E--Surgical Devices

Sec. 878.4020 Occlusive wound dressing.

(a) *Identification.* An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gases such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an adhesive backing. This classification does not include an occlusive wound dressing 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]

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