



U.S. Food and Drug Administration



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Product Classification Database

Device	Binder, Breast
Device Description	Therapeutic medical binder.
Medical Specialty	General Hospital
Product Code	HEF
Regulation Number	<u>880.5160</u>
Device Class	I
GMP Exempt?	Yes

Note: This device is also exempted from the GMP regulation, except for general requirements concerning records (820.180) and complaint files (820.198), as long as the device is not labeled or otherwise represented as sterile.

510(k) Exempt? Yes

Note: FDA has exempted almost all class I devices (with the exception of Reserved Devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with [21 CFR Parts 862-892](#). Limitations of device exemptions are covered under [21 CFR xxx.9](#), where xxx refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in [21 CFR Parts 862-892](#), a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, these manufacturers are required to register their establishment by submitting Form FDA 2891, "Initial Registration of Device Establishment," and list the generic category or classification name of the device by submitting Form FDA 2892, "Device Listing."

Database Updated 9/5/2003