



Posey Company

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FAQ No.: 22

FAQ: Where can I get a copy of the 510K for the Posey Bed Canopy System

The Posey Bed Canopy System is classified as an “accessory for AC-Powered adjustable hospital bed per FDA Regulation 21CFR 880.5100. “Devices covered by this regulation are exempt from the premarket notification procedures (510K).” Therefore, there is no 510K for this device. However, the device is listed with the FDA as required. See attached copy of FDA Device Listing Database web page.

Sec. 880.5100

(a) Identification. An AC-Powered adjustable hospital bed is a device intended for medical purposes that consist of a bed with a built-in electronic motor and remote controls that can be operated by the patient to adjust the height and surface contour of the bed. The device includes movable and latchable side rails.

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to Sec. 880.9.

[45 FR 69682-69737, Oct 21, 1980, as amended at 64 FR 59229, Nov. 3, 1998]

For complete cleaning and use instructions for all Posey products, please refer to package insert accompanying each product. Copies of all package insert instructions are available on the Posey website at www.posey.com.

We hope that this answers your questions. If you have any further questions, please feel free to call Posey Customer Service at (800) 44-Posey or (800) 447-6739.



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Device Listing Database

Proprietary Device Name: POSEY BED ENCLOSURE
Common/Generic Device Name: HOSPITAL BED ACCESSORY
Classification Name: BED, AC-POWERED ADJUSTABLE HOSPITAL
Device Class: 2
Product Code: FNL
Regulation Number: 880.5100
Medical Specialty: General Hospital
Owner/Operator: J. T. POSEY CO.
Owner/Operator Number: 2020362
Registered Establishment Name: J. T. POSEY CO.
Establishment Registration Number: 2020362
Date of Listing: 06/13/02
Listing Status: Active
Establishment Operations: Manufacturer

Database Updated 3/08/2005

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<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/Listing.cfm?ID=16551>

3/23/2005