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510(K) SUMMARY

JJ Skinner CareKits™  
Wound Care Management/Dressing Change Tray

Submitter Information:

JJ Skinner Inc.  
Stark Bldg. Suite 825  
455 South Fourth Avenue  
Louisville, KY 40202

510(k) Summary Prepared By:

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Date 510(k) Summary Prepared: March 20, 1996

Name of the Device:

Trade or Proprietary Name: JJ Skinner CareKits™ Wound Care Management/Dressing Change Tray

Common Name: Wound care kit/tray; dressing change kit/tray

Classification Name: Kit, Wound Dressing (Product Code: 79MCY)

Identification of Legally Marketed Device to which the Submitter Claims Equivalence:

The JJ Skinner CareKits™ Wound Care Management/Dressing Change Tray is an assembly of medical products sterilized within a Tyvek®/polyethylene pouch. The trays are sterile, disposable, and single use. The primary purpose is for the convenience of the Healthcare professional. The trays are custom to the customer, and include a variety of medical devices that are legally marketed, are exempt, or are grandfathered. These components of the tray are commonly used for wound

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management, and JJ Skinner is not claiming or causing new uses through the intended use of the tray.

**Intended Use of the Subject Devices:**

The JJ Skinner CareKits™ Wound Care Management/Dressing Change Tray is intended to be used by Healthcare professionals for wound care management, including, cleansing, irrigation, debridement, and dressing changes.

**Technological Characteristics of the Subject Device:**

The technological characteristics of JJ Skinner CareKits™ Wound Care Management/Dressing Change Trays and the predicate device are substantially equivalent as supported by the comparison of similar significant features, components, and intended use.

No clinical evaluations were completed.