

K961683

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ATTACHMENT 1

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510(K) SUMMARY

JJ Skinner CareKits™
Minor Surgical Procedure Tray/Kit

Submitter Information:

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510(k) Summary Prepared By:

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Date 510(k) Summary Prepared: April 25, 1996

Name of the Device:

Trade or Proprietary Name: JJ Skinner CareKits™ Minor Surgical
Procedure Tray

Common Name: Custom Minor Surgical Procedure Tray/Kit

Classification Name: Tray, Surgical, General Product Code: 79LRP)

DEVICE DESCRIPTION

The devices are an assembly of medical products within Tyvek®/polyethylene breather pouch. The medical products include medical devices, and drugs that are 510(k) approved devices, grandfathered, or exempt. The primary purpose of the assembly is for the convenience of the Medical practitioner. The kit is sterile, single use and disposable.

The kits are custom made for the customer, who specifies the name of the kit (i.e.) as well as the contents. Attachment 5 includes a list of the medical components that may be requested by the customer.

Identification of Legally Marketed Device to Which Submitted Substantial Equivalence:

The JJ Skinner CareKits™ Minor Surgical Procedure Tray/Kit is substantially equivalent in intended use and contents to trays legally marketed. Several companies including JJ Skinner's CareKits™ approved under K903545.

Intended Use of the Subject Devices:

The JJ Skinner CareKits™ Minor Surgical Procedure Tray/Kit is intended to be used by Healthcare professionals for minor surgical procedures. Minor surgical procedures are those generally performed on an outpatient basis, under topical anesthetics. These may include dermatological excisions or circumcisions.

Technological Characteristics of the Subject Device:

The technological characteristics of JJ Skinner CareKits™ Minor Surgical Procedure Tray/Kit 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.