

OCT -7 1996

K962849

(1) **510(k) Summary:**

This summary is submitted in conformance with the format described in the 21 CFR Part 807.92 interim rule dated April 28, 1992.

(1) **Submitted By:**

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Contact Person:

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(2) **Name of Device:**

Catheter Insertion Tray

Classification Name:

Unknown

(3) **Identification of Predicate Devices:**

Catheter Insertion Tray (510(k) No. K936261)
Prep Tray - PICC Insertion Cat No. DP2-2150

MedCare Medical Group, Inc.
E. Swanzey, NH 03446

(4) Description of Device Subject to Premarket Notification:

The Catheter Insertion Tray is intended to conveniently provide the components used to aid the insertion of percutaneous catheters such as: TPN/CVP catheters, PICC Line catheters, and Long Line catheters. The Catheter Insertion Tray provides the convenience of having these commonly used items packaged in a single package, sterile, and ready to use. The kits are provided sterile, disposable, and for single patient use.

(5) Intended Use of the Device:

The Catheter Insertion Tray is a single patient, single use, disposable device which is intended to conveniently provide components to aid in the administration of percutaneous catheterization.

(6) Technological Characteristics

The MedCare Catheter Insertion Tray is similar to the predicate device in that both of the device provide a variety of auxiliary components for the convenient administration of percutaneous catheterization. Both devices provide flexibility in componentry selection for kit customization, which provides the maximum convenience for the customer. The proposed Catheter Insertion Tray will provide additional convenience by offering the inclusion of a vessel dilator and guide wire to the tray.