

K961075

SEP - 6 1996

(I) **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:**

Regional Anesthesia Kit

Classification Name:

Anesthesia Conduction Kit

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

Regional Anesthesia Kits:

1. Spinal
2. Epidural/Caudal
3. Nerve Block

- (a) **Kendall HealthCare Products Company
Mansfield, MA 02048**

(4) **Description of Device Subject to Premarket Notification:**

The MedCare Medical Group Regional Anesthesia Kit is a disposable, single patient, single use device for the administration of regional anesthesia. The componentry within the kit will vary depending on the customers requirements and the type of regional anesthesia procedure being performed; spinal, epidural-caudal, or nerve block.

(5) **Intended Use of the Device:**

The MedCare Regional Anesthesia Kit is a single patient, single use, disposable device which is intended to be used for the administration of regional anesthesia.

(6) **Technological Characteristics**

The MedCare Regional Anesthesia Kit is similar to the predicate devices in that all of the devices provide a variety of components for the administration of regional anesthesia. All the devices provide flexibility in componentry selection for customization to the user and the particular type of regional anesthesia being performed; spinal, epidural-caudal, or nerve block.