

K954706

EXHIBIT #7

MAY 30 1996

510(k) Summary

Kendall Blunt Tip Tuohy Epidural Needle

In accordance with Section 513(I)(3) of the SMDA and as described in 21 CFR Part 807.92 interim rule dated April 28, 1992, this summary is submitted by:

Kendall Healthcare Products Company
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Date: February 20, 1996

1. Contact Person

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2. Name of Medical Device

Classification Name: Anesthesia Conduction Needle
Common or Usual Name: Blunt Tip Epidural Needle
Proprietary Name: Kendall Blunt Tip Tuohy Epidural Needle

3. Identification of Legally Marketed Device

The Kendall Blunt Tip Tuohy Epidural Needle is substantially equivalent in composition, form, function and intended use to the commercially available Kendall 18 Gauge Calibrated Tuohy Epidural Needle (K921288B).

4. Device Description

The Kendall Blunt Tip Tuohy Epidural Needle is a sterile single use device designed to be used for the induction of epidural anesthesia. The needle cannula and matched stylet are composed of stainless steel. A polycarbonate hub is insert molded onto the cannula. The hub is supplied in two configurations, a fixed wing design and a non-winged design. The cannula gauge, length and tip are equivalent to current commercially available epidural needles. A portion of the tip of a standard needle bevel is removed in a blunt grind process. The sharp cutting edges around the periphery of the needle bevel remain unchanged.

5. Device Intended Use

Like other commercially available epidural needles, the Kendall Blunt Tip Tuohy Epidural Needle is used to administer anesthetic to the peridural space.

6. Product Comparison

The Kendall Blunt Tip Tuohy Epidural Needle is equivalent to the referenced predicate device in that they are fabricated from identical materials, have the same function and equivalent indications for use.

7. Nonclinical Testing

Biocompatibility testing was performed on the needle hub following ISO-10993 Biological Evaluation of Medical Devices. This testing found the material contained no toxic diffusible substances.

Functional/Mechanical testing was performed to determine needle penetration force and hub pull-off force.

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