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510(k) Notification - Alexander Medical
Epidural Kit and Combined Spinal/Epidural Kit

K964783

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On behalf of :
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9055 N.W. 13th Court
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**Name(s) of the device: Epidural and Combined Spinal/Epidural Kits**

**Identification of predicate device(s):**

Combined spinal/epidural kits have been introduced to the U.S. market in the 1990's, and many have received FDA approval. These include B. Braun's Espocan Combined Spinal Needle Set and Tray (K932400, K932569), Neurodelivery's Combined E-Sp (K933711), Preferred Medical's Epi-Spinal Tray and Miniset (K925014), Kendall Safetrak Combined Ep/Sp (K941493), Mediziv Regional Anesthesia Tray (K932614), and Becton Dickinson's "Durasafe" combined Spinal/Epidural Anesthesia Kit (K920076). The components vary from kit to kit, but the catheter is the same as Becton Dickinson's Durasafe.

Epidural kits have been marketed since before the medical device amendments, and many have received FDA clearance. These include epidural kits by Spinal Specialties, Kendall, Becton Dickinson, Preferred Medical, and many others. The components included in Alexander Medical's epidural kits are essentially the same. There are no new indications for use or claims made for the kits or the components contained in the kits.

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**Description of the device:**

The Epidural kit includes an epidural needle (Eldor combined spinal/epidural), epidural catheter, Touhy-Borst Adapter, Loss of resistance syringe, and Epidural. The epidural/spinal combined kit includes the same components and adds a pencil point spinal needle.

**Intended Use**

Delivery of Epidural anesthesia for the epidural kits and delivery of combined spinal/epidural anesthesia for the combined kits.

**Comparison of device characteristics to predicate**

Epidural and combined spinal/epidural kits are not new to the U.S. market. All the components used in Alexander Medical's kits are legally marketed components and most are included in various combinations with other epidural and combined spinal/epidural kits legally on the market.

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The technological characteristics of the combined spinal/epidural kit as compared to the predicate devices are essentially the same. The Eldor needle is already cleared through the FDA, and is essentially similar to Neurodelivery's E-Sp (K933711), except the tubular needle guide is shorter than the Neurodelivery device. B. Braun's Espocan in K932400 is also similar, except the tubular guide is within the epidural needle and a back hole is added for passage of the needle. The extra lumen is small enough to not allow an epidural catheter to pass through while allowing passage of a 26 gauge needle. The feature of the Eldor and Neurodelivery needles is that the tubular needle guide is on the outside of the epidural needle, and there is no back hole in the epidural needle as with B. Braun's Escopan. Drawings and more detailed information are available in K935255, the 510(k) for the Eldor needle. This 510(k) is for kits utilizing the Eldor needle.

The Kendall Safetrak Combined Ep/Sp K941493, The Mediziv Regional Anesthesia Tray K932614, and the Becton Dickinson Durasafe K920076 kits also contain components needed for both epidural and spinal anesthesia procedures. These combined epidural/spinal kits involve a two needle technique allowing a spinal anesthetic to be given for intraoperative anesthesia while an epidural catheter is placed for post-op analgesia for up to 72 hours. The product consists of a longer spinal needle which can be passed through a traditional epidural needle. To perform this procedure, the epidural space is located with a Touhy epidural needle. The 26 gauge pencil point needle is passed through the lumen of the epidural needle out the tip and advanced through the dura matter to access the subarachnoid space. The 26 gauge spinal needle passes through the 17 gauge epidural needle because of the difference in size between the outside diameter of the spinal needle and the inside diameter of the epidural needle. A spinal block is administered through the spinal needle, which is then removed, leaving the epidural needle in place. The epidural catheter is threaded through the epidural needle into the epidural space to the desired depth and the epidural needle is removed. The Becton Dickinson and Kendall devices include a 17 gauge epidural needle and a 24 gauge spinal needle. These predicates include a 20 gauge catheter that is inserted into the patient through the epidural needle for epidural anesthesia.

**Table of Technological Characteristics**

| Device Name | DEVICE<br>Alexander Medical Epidural and Combined Spinal/Epidural Kits | PREDICATE<br>Becton Dickinson Durasafe | PREDICATE<br>Mediziv Epidural Set and Tray and the Regional Anesthesia Tray | |
|---|---|---|---|---|
| **510(k) numbers** | NEW- This submission | K920076 | K932614 Regional (Combined)<br>K894725 Epidural Tray | |
| **Indications for use** | Epidural and/or Spinal Anesthesia | Same | Same | |
| **Warnings / Precautions** | 1) Withdrawing epidural catheter through needle<br>2) limit to 72 hours of use<br>3) warning about interthecal medications | Same | Same | |
| ***Components*** | 1) Eldor needle with conduit outside epidural needle K935255<br>2) 20 gauge 3 hole epidural catheter - K840202<br>3) Touhy Borst Adaptor - Preamendment<br>4) 27 gauge pencil point Spinal Needle - K944905 (not in Epidural Kit)<br>5) Epidural Filter - Preamendment<br>6) Loss of resistance syringe - Preamendment<br>NO DRUGS, NO GLOVES<br><br>Epidural Kit includes all item except #4 | 1) Epidural needle with back eye hole<br>2) 20 gauge 3 hole epidural catheter<br>3) Touhy Borst Adaptor<br>4) 25 gauge pencil point needle<br>NO DRUGS, NO GLOVES | Combined<br>1) Epidural Needle<br>2) 17 gauge 3 hole epidural catheter<br>3) no adaptor<br>4) 26 gauge pencil point needle<br>5) epidural filter<br>6) Loss of resistance syringe<br>7) Drugs and other components | Epidural<br>1) Epidural needle<br>2) Epidural Catheter<br>3) Epidural Filter<br>4)Loss of resistance syringe |
| **Materials** | Needles - Stainless Steel<br>Catheter - Polyamide Nylon | Same | Same | |
| **Certifications** | See section 12 for Kit Certification and truth and accuracy statement | NA | NA | |
| **Biocompatibility** | All components are legally marketed and are made with biocompatible materials | All components are legally marketed materials | All components are legally marketed materials | |

**Conclusion:** All components are legally marketed, and other devices with the same or similar components and same intended use are legally on the market. The kits are substantially equivalent.