

SUMMARY OF SAFETY AND EFFECTIVENESS

Becton Dickinson and Company

BD DURASAFE™ CSE TRAY WITH STELLA-CATH™

1.0 **BD CONTACT PERSON**

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2.0 **DEVICE NAME**

BD *Stella-Cath*™ Combined Spinal/Epidural (CSE) Kit/Tray

3.0 **PREDICATE DEVICE**

BD *Durasafe*™ Combined Spinal Epidural Anesthesia Needle Set/Kit (K932249)

4.0 **PRODUCT DESCRIPTION / FUNCTION**

4.1 **Description** - The only change described in this 510(k) is replacing the epidural catheter with the *Stella-Cath*™ Epidural Catheter, a nylon epidural catheter with star shape internal profile.

4.2 **Function** - The subject device will function the same as predicate devices.

5.0 **COMPARISON OF MODIFIED AND PREDICATE DEVICES EQUIVALENCE**

5.1 **Descriptive Comparison To a Legally Marketed Device**

The predicate, legally marketed device is the BD *Durasafe*™ Combined Spinal/Epidural Anesthesia Needle Set/Kit (FDA 510(k) # K932249).

The subject device, BD *Stella-Cath*™ Combined Spinal/Epidural Kit/Tray is **identical** to the predicate device in all respects with the **exception of the internal profile of the epidural catheter.**

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5.2 Performance Data Supporting Substantial Equivalence

The mechanical testing results show that the BD Stella-Cath™ catheter meets all the specification requirements, and is not any inferior than the current product in any aspects. All components in the kit conform to the physical mechanical and biological specifications found in the product standards referenced below.

ISO 594	Conical Fittings with a 6% (LUER) Taper
ISO 7864	Sterile Disposable Needles
ISO 7886-1	Sterile Disposable Syringes
ISO 10993-1	Biological Evaluation of Medical Devices Part I: Guidance on Selection of Tests

5.3 Reference Table A For Comparison Table

This summary of Safety and Effectiveness data is being submitted in compliance with the Safe Medical Device Act.

TABLE A

See next page

TABLE A

Side-by-Side Comparison Table

ELEMENT OF COMPARISON	B-D DURASAFE™ COMBINED SPINAL EPIDURAL (CSE) KIT/TRAY WITH STELLA-CATH™ (SUBJECT DEVICE)	B-D DURASAFE™ COMBINED SPINAL EPIDURAL (CSE) NEEDLE SET/KIT (PREDICATE DEVICE)
1. Intended Uses	same as the predicate device	Regional Anesthesia: To provide a device to accomplish the Combined Spinal (CSE) Epidural Technique
2. Gauge Sizes: Spinal Needle Epidural Needle	same as the predicate device	25/27G 17/18G
3. Tip Configuration: Spinal Needle Epidural Needle	same as the predicate device	Whitacre or Quincke Point Tuchy-Shliff Point
4. Accessories (in the kit models)	same as the predicate device	Catheter, Tuchy Borst Adapter, Filter, LOR Syringe
5. Colors: Spinal Hubs Spinal Handles Epidural Hubs Epidural Handle/Stylet	same as the predicate device	Reed Blue (25G) Reed Blue (25G) None Reed Gray (17G); Pink (17G)
6. Cannula Strength	same as the predicate device	Federal Stiffness Test
7. Needle Bond Strength	same as the predicate device	8 lb. minimum
8. Biocompatibility	same as the predicate device	ISO
9. Materials	same as the predicate device	Approved
10. Labeling	added tradename to packaging labels. No change in Direction for Use.	Provide Labels and Direction for Use where appropriate.