

510(k) Summary of Safety & Efficacy: Sensi-Touch™ Combo Spinal/Epidural Regional Anesthesia Delivery System

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The Sensi-Touch™ Combo Spinal/Epidural Regional Anesthesia Delivery System will include all components commonly required to perform both a spinal and epidural procedure in a sterile, single use procedure-ready package. This procedure tray will be available in several configurations of tray components. This device is a Class II device per 21 CFR 868.5140, Prococode: 73CAZ.

The combo tray is intended for Surgical or OB regional anesthesia blocks. The rationale for combining the epidural and spinal needles into one kit is as follows; an epidural block takes approximately 25 minutes for onset of the anesthetic, whereas, a spinal block takes approximately 5 min. for onset of anesthetic. Therefore, the patient benefits from both quick pain relief associated with a spinal and long-term pain relief associated with an epidural.

The procedure is as follows, the clinician will first place the epidural needle in the patient's epidural space. The spinal needle is then inserted through the epidural needle into the spinal cavity. The anesthetic is then administered through the spinal needle for quick pain relief. The spinal needle is then removed and an epidural catheter is inserted through the epidural needle into the epidural space. The catheter provides a conduit for the administration and re-administration of anesthetic into the epidural space to provide long term pain relief.

The Sensi-Touch™ Combo Spinal/Epidural Regional Anesthesia Delivery System is substantially equivalent to Sherwood Medical's currently marketed Sensi-Touch Epidural Anesthesia Delivery System (preamendment & #K950929) and Sensi-Touch Spinal Trays (preamendment) in that they both contain the components commonly required to place an anesthesia needle for regional anesthesia. Furthermore, the proposed tray will contain both a Tuohy Epidural Needle and a Whitacre Spinal Needle (currently marketed needles).

The major difference is that the currently marketed spinal and epidural trays are separate in that a tray either contain a spinal or epidural needle, not both.

The Sensi-Touch™ Combo Spinal/Epidural Regional Anesthesia Delivery System is substantially equivalent to the Durasafe Combined Spinal Epidural Sets (cleared via the 510(k) process, #K932249) in that they both have the same intended use and basic components.

The Sensi-Touch™ Combo Spinal/Epidural Regional Anesthesia Delivery System is substantially equivalent to the Espocan Combined Spinal/Epidural Sets (cleared via the 510(k) process, #K932400) in that they both have the same intended use and basic components.