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SMITHS INDUSTRIES
Medical Systems

SIMS Inc.

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H: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY

COMPANY INFORMATION

Smiths Industries Medical Systems, Inc.
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Timothy J. Talcott
Manager of Regulatory Affairs

PREPARATION DATE OF SUMMARY

December 13, 1996

TRADE NAME

None

COMMON NAME

Regional Anesthesia Trays

CLASSIFICATION NAME

Class II, 73CAZ, 21 CFR 868.5140
Note: This device may also be classified under General Hospital as a "prolonged contact device, >24 hours to 30 days.

PREDICATE DEVICE

The proposed modification to our Regional Anesthesia Trays is substantially equivalent to the predicate devices;

- Continuous Epidural Tray, without Drugs, Full Kits
- Continuous Epidural Tray, with Drugs, Full Kits
- Continuous Epidural Tray, without Drugs, Mini-Pack
- Single Shot Epidural Tray, without Drugs
- Single Shot Epidural Tray, with Drugs
- B-D Whitacre Spinal Trays, without Drugs
- B-D Whitacre Spinal Trays, with Drugs
- B-D Quincke Spinal Trays, with Drugs
- Pediatric Continuous Epidural/Caudal Systems
- Pediatric Single Shot Epidural/Caudal Systems
- Combined Epidural/Spinal Trays, without Drugs
- Combined Epidural/Spinal Trays, with Drugs
- Catheter Connector

DESCRIPTION

Regional Anesthesia Trays cover a broad product range, including; Continuous Epidural, Single Shot Epidural, Spinal, Nerve Block, Pediatric Epidural, and Combined Spinal/Epidural Trays. These trays are a compilation of the preparatory and surgical components required for administering anesthesia. The trays may include components such as; needles, syringes, filters, catheters, gloves, gauze sponges, drapes, and drugs. The components are placed into a plastic tray, wrapped in CSR wrap, sealed, and sterilized by ethylene oxide.

The trays are available in standard component configurations or can be customized to meet the needs of an individual user. All componentry supplied in these kits are from an approved list of components which are legally marketed devices.

INDICATIONS FOR USE

SIMS' Regional Anesthesia Trays are used to administer to a patient regional or local anesthesia.

TECHNOLOGICAL CHARACTERISTICS

All components used in our Regional Anesthesia Trays are legally marketed devices. The inclusion of these components in these trays will have the same biocompatibility implications as their current usage. The modified epidural catheter connector housing is constructed of the same materials as is currently used in the device. The insert does not contact the patient or the fluid path, as such, there are no toxicological implications with the insert.

SUMMARY OF PERFORMANCE DATA

Testing of the epidural catheter connector was performed in accordance with BS 6196. Performance testing of the proposed modification to the epidural catheter connector demonstrates that it performed equal to or better than our current epidural catheter connector.

SUMMARY OF NONCLINICAL AND CLINICAL TESTS

There were no nonclinical or clinical tests submitted with this submission.

CONCLUSION OF NONCLINICAL AND CLINICAL TESTS

There were no nonclinical or clinical tests submitted with this submission.

ADDITIONAL INFORMATION

None

Very truly yours,

Smiths Industries Medical Systems, Inc.
dba Concord/Portex

Timothy J. Talcott
Manager of Regulatory Affairs