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SIMS Inc.
15 Kit Street
Keene, NH 03431
Telephone: (603) 352-3812
Fax: (603) 352-3703

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H: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY

COMPANY INFORMATION

Smiths Industries Medical Systems, Inc.
15 Kit Street
Keene, NH 03431
(603) 352-3812 x457
(603) 357-5038
Timothy J. Talcott
Manager of Regulatory Affairs

PREPARATION DATE OF SUMMARY

September 4, 1996

TRADE NAME

SIMS Adult (Pediatric) Lumbar Puncture Kit
SIMS Adult (Pediatric) Lumbar Puncture Kit with Manometer

COMMON NAME

Adult (Pediatric) Lumbar Puncture Kit
Adult (Pediatric) Lumbar Puncture Kit with Manometer

CLASSIFICATION NAME

Class II, 80 FMJ, 21 CFR 880.2500

PREDICATE DEVICE

American Pharmaseal® Company's Pediatric/Infant Lumbar Puncture Tray
Abbott Laboratories' Lumbar Puncture, Child, 22-G x 3 1/2", Double-Decker Tray with Lidocaine Hydrochloride
Abbott Laboratories' Lumbar Puncture, Adult, 20 -G x 3 1/2", Double-Decker Tray with Lidocaine Hydrochloride

DESCRIPTION

The SIMS Lumbar Puncture (LP) Kit is available in adult or pediatric configurations. The kit includes the preparatory and procedural components to perform Lumbar Puncture. A manometer may be included with the kit, depending upon the kit selected.

The SIMS LP Kits with a manometer are used to measure cerebrospinal fluid pressure in centimeters of water (cm of H2O). The manometer consists of two calibrated sections of tubing with a connector welded to the upper portion of the tubing.

The SIMS LP Kits are intended to be used when Lumbar Puncture is performed to obtain a CSF specimen for diagnostic study when possible CNS infection is suspected, such as sepsis and/or meningitis. The procedure can also be used to measure increased intracranial pressure which can result from infection, tumor, hemorrhage or edema. This technique is also used to lower intracranial pressure by CSF drainage. CSF pressure is measured prior to CSF sampling using a manometer.

Lumbar puncture is performed with standard prep and procedural componentry, similar to those used in spinal anesthesia kits, with the addition of a two part manometer, a 3-way stopcock and 5 inches of small bore extension tubing for the measurement of intracranial CSF pressure.

INDICATIONS FOR USE

The SIMS Lumbar Puncture (LP) Kit is indicated for sampling of Cerebrospinal Fluid (CSF) and the measurement of CSF pressure as indicated in standard textbooks[1,2,3].

The SIMS LP Kits are intended to be used when Lumbar Puncture is performed to obtain a CSF specimen for diagnostic study when possible CNS infection is suspected, such as sepsis and/or meningitis. The procedure can also be used to measure increased intracranial pressure which can result from infection, tumor, hemorrhage or edema. This technique is also used to lower intracranial pressure by CSF drainage. CSF pressure is measured prior to CSF sampling using a manometer.

References:

1. Isselbacher KJ, Harrison's Principles of Internal Medicine, 10th Ed., McGraw-Hill, 1994; New York.
2. Adams RD, Victor M., Principles of Neurology, 5th Ed., McGraw-Hill, 1993; New York.
3. Wyngaarden JB, Cecil, Textbook of Medicine, 19th Ed., W.B.Saunders, 1992; Philadelphia.

TECHNOLOGICAL CHARACTERISTICS

All components for the proposed LP kits, except the manometer and extension set, are legally marketed devices, marketed separately and/or contained in legally marketed devices for Pediatric Regional Anesthesia Systems, Spinal Anesthesia Systems, or Epidural Anesthesia Systems marketed under 510(k) K851134. The manometer is made of a biocompatible plastic used extensively in other medical devices. The extension set is made of materials used in our existing blood pressure monitoring tubing, K833171.

SUMMARY OF PERFORMANCE DATA

Performance testing of the proposed kits show the SIMS manometer performed equal to or better than the predicate manometer from Abbott, both for the range in accuracy and for the average variance in accuracy.

SUMMARY OF NONCLINICAL AND CLINICAL TESTS

There were no nonclinical or clinical tests performed with these kits.

CONCLUSION OF NONCLINICAL AND CLINICAL TESTS

There were no nonclinical or clinical tests performed with these kits.

ADDITIONAL INFORMATION

None

Very truly yours,

Smiths Industries Medical Systems, Inc.
dba Concord/Portex

Timothy J. Talcott
Manager of Regulatory Affairs