

10081404

OCT 21 2008

Spinal Integration, LLC

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510k SUMMARY

Company Information: Spinal Integration LLC
6314 Kingspointe Pkwy Unit 6
Orlando, Florida 32819
Telephone: (800) 937-7949
Facsimile: (407) 392-4133
Contact: Dan Becker
General Manager

Summary Prepared: May 15, 2008

Device Identification:

Proprietary/Trade Name: Spinal-EZE™ Intraoperative Epidural Catheter Kit
Common/Usual Name: Anesthesia Conduction Catheter
Classification Name: Catheter, Conduction Anesthetic
Device Class: Class II
Device/Product Code: BSO
Regulation Number: 21CFR 868.5120
Classification Panel: Anesthesiology

Predicate Devices: Intra Op Catheter, I-Flow Corporation, BSO, (K991543)
Epidural Catheter, Aries Medical, Inc. (Teleflex Medical)
BSO, (K840202)

Indications for Use: The Spinal-EZE™ Intraoperative Epidural Catheter Kit is intended to provide intraoperative single dose delivery of local anesthetic and/or narcotics to the epidural space adjacent to the cauda equina when the epidural injection location is accessible as a result of surgery to the spinal column through the epidural space. The only clinical setting for administration for the Spinal-EZE™ Intraoperative Epidural Catheter is intraoperative. The device is provided sterile and is intended for single-use only.

Device Description: The Spinal-EZE™ Intraoperative Epidural Catheter Kit consists of a catheter assembly with a .027" ID x .060" OD that is 60 cm long with an atraumatic bullet shaped closed tip. The catheter has depth marks at 100mm increments and 6 pairs of punched holes .56mm to .61mm in diameter positioned 90° apart at 3mm increments

beginning 19.99mm from the catheter tip. The catheter is manufactured from 60 durometer Barium sulfate loaded (5%) silicone elastomer. Also included in the kit is a 10cc Syringe marked "epidural", a blunt tip 65cm long Teflon coated guide wire to assist in maneuvering the catheter during insertion, a Luer lock and cap assembly to facilitate attachment of the catheter to the syringe.

Substantial Equivalence: The substantial equivalence of the Spinal-EZE™ Intraoperative Epidural Catheter is supported by its similarities in design features, performance and indications for use to the Intra Op Catheter, I-Flow Corporation (K991543) and the Epidural Catheter, Aries Medical, Inc. (Teleflex Medical) (K840202)

Technical Characteristics: This device and its predicates are closed end with lateral/radial side hole catheters intended for intraoperative use. The Spinal-EZE™ Intraoperative Epidural catheter's fluid path materials are in conformance with ISO 10993 part 1 for Fluid path contact as are the predicates Intended use, precautions, contraindications, sterilization method, labeling and packaging of the subject device and its predicates indicate to Spinal Integration that the Spinal-EZE™ Intraoperative Epidural Catheter Kit is substantially equivalent to the named predicate devices.

Summary of Testing: All materials used in the fabrication of the Spinal-EZE™ Intraoperative Epidural Catheter were evaluated through biological qualification safety tests as outlined in ISO 10993-1 Part 1 "Biological Evaluation of Medical Devices". Design control activities have been completed and the results indicate that the subject device is safe and effective.

Conclusion: The above statements are accurate representations of the device Spinal Integration intends to market. Based on all the testing and comparison Spinal Integration believes the subject device is substantially equivalent to the predicate devices. All data and information submitted in this premarket notification is truthful and accurate and no material fact has been omitted.



OCT 21 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Trudie Seeger
Regulatory Consultant
Spinal Integration, LLC
6314 Kingspointe Parkway Unit 6
Orlando, Florida 32819

Re: K081404
Trade/Device Name: Spinal-EZE™ Intraoperative Epidural Catheter Kit
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: II
Product Code: BSO
Dated: September 30, 2008
Received: October 2, 2008

Dear Dr. Seeger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", with a date "7/20/01" written below it.

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K081404

Device Name: Spinal-EZE™ Intraoperative Epidural Catheter Kit

Indications for Use: The Spinal-EZE™ Intraoperative Epidural Catheter Kit is intended to provide intraoperative single dose delivery of local anesthetic and/or narcotics to the epidural space adjacent to the cauda equina when the epidural injection location is accessible as a result of surgery to the spinal column through the epidural space. The only clinical setting for administration for the Spinal-EZE™ Intraoperative Epidural Catheter is intraoperative. The device is provided sterile and is intended for single-use only.

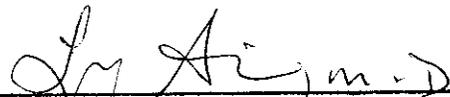
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081404