

K043467

MAR 31 2005

Section II

510(K) Summary

**Company Information:**

Epimed International, Inc.  
141 Sal Landrio Drive  
Johnstown, NY 12095  
(518) 725-0209  
Contact: Christopher B. Lake  
Manager of RA/QA

**Trade Name:**

Flexible Spinal Needle

**Common Name:**

Flexible Spinal Needle

**Product Class/Classification:**

Class II

**Predicate Device(s):**

Epimed Quincke Spinal Needle (K022029)  
Custom Medical Concepts Spinal Cord Access Epidural Introducer System  
(K904380)

**Description:**

The Flexible Spinal Needle consists of a coated flexible stainless steel cannula with a molded plastic hub. A stylet is also provided with the device which consists of a stainless steel cannula and a molded plastic hub.

The Flexible Spinal Needle will be provided as a sterile, single use, disposable device and will be available in a variety of lengths and gauges.

**Intended Use:**

For the administration of anesthetic agents to provide regional anesthesia.

**Comparison to Predicate:**

The Flexible Spinal Needle has similar characteristics attributes to both the Epimed Quincke Spinal Needle marketed under K022029 and the Custom Medical Concepts Spinal Cord Access Epidural Introducer System marketed under K904380.

**Non-Clinical Data:**

Bench Testing performed on the Flexible Spinal Needle to compare performance characteristics to the predicate device(s) confirmed that the performance of the Flexible Spinal Needle is similar to the predicate device(s).

**Conclusion:**

The comparison to the predicate device(s) demonstrates that the Flexible Spinal Needle is safe and effective and is substantially equivalent to the predicate device(s).

Very truly yours,

Epimed International, Inc.



Christopher B. Lake  
Manager of Quality Assurance/Regulatory Affairs



MAR 31 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Christopher B. Lake  
Manager of Regulatory Affairs/Quality Assurance  
Epimed International, Incorporated  
141 Sal Landrio Drive  
Crossroads Business Park  
Johnstown, New Jersey 12095

Re: K043467  
Trade/Device Name: Flexible Spinal Needle  
Regulation Number: 868.5150  
Regulation Name: Anesthesia Conduction Needle  
Regulatory Class: II  
Product Code: BSP  
Dated: February 21, 2005  
Received: February 24, 2005

Dear Mr. Lake:

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.

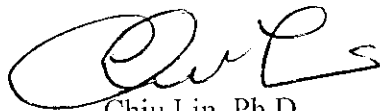
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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): unk

Device Name: Flexible Spinal Needle

Indications for Use:

The Flexible Spinal Needle is intended for the administration of anesthetic agents to provide regional anesthesia.

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  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Arzu Salim*

Arzu Salim  
Division Sign-Off  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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