510(k) Summary

MAR 1 8 2009

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax Number of Applicant

Laurimed LLC
500 Arguello Street, Suite 100
Redwood City, CA 94063
Phone: (650) 587-5296
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B. Contact Person

Sevrina Ciucci
Regulatory Affairs Consultant
(408) 316-4837

C. Date Prepared

December 26, 2008

D. Device Name

Trade Name:	Spinal Injection System
Common Name:	Needle, Conduction, Anesthetic (w/wo introducer)
Classification Name:	Anesthesia Conduction Needle (21 CFR §868.5150, Product Code BSP)

E. Predicate Devices

The Laurimed Spinal Injection System is substantially equivalent to the Laurimed Spinal Injection System (K080140).

F. Device Description

The Laurimed Spinal Injection System integrates a flexible Catheter with an atraumatic distal tip into a Needle designed for injections/infusions of contrast media, anesthetics, and anti-inflammatory medications into the epidural space of the spine.

The Spinal Injection System is supplied as a sterile, single patient use, disposable device.

Intended Use

The Laurimed Spinal Injection System is intended for use in procedures where injection is required.

The Laurimed Spinal Injection System is indicated for use in spinal epidural injections for the administration of contrast media, anesthetic agents to provide regional anesthesia, and anti-inflammatory medications. Not for use with other needles or catheters.

G. Technological Comparison

The technological characteristics and principals of operation of the Laurimed Spinal Injection System are substantially equivalent to the noted predicate device.

H. Summary of Non-Clinical Data

Results of non-clinical testing demonstrated that the Spinal Injection System is safe and effective for its intended use.

I. Summary of Data

The Spinal Injection System has been carefully compared to a legally marketed device with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the Spinal Injection System functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

NOV 22 2009

Ms. Sevrian Ciucci
Regulatory Affairs Consultant
Laurimed LLC
500 Arguello Street, Suite 100
Redwood City, California 94063

Re: K083909
Trade/Device Name: Spinal Injection System
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: December 26, 2008
Received: December 30, 2008

Dear Ms. Ciucci:

This letter corrects our substantially equivalent letter of March 18, 2009.

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 (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 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) 276-0120. 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,

Ginette Y. Michaud, M.D.
Acting 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 Statement

510(k) Number (if known): K_____

Device Name: Spinal Injection System

Indications for Use:

Spinal epidural injections for the administration of contrast media, anesthetic agents to provide regional anesthesia, and anti-inflammatory medications. Not for use with other needles or catheters.

Prescription Use ___X___ **OR** **Over-The-Counter Use**_____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sara Runner

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

510(k) Number: K083909