510(k) Summary

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
Fax: (650) 587-3823

B. Contact Person

Sevrina Ciucci
Regulatory Affairs Consultant
(408) 316-4837

C. Date Prepared

September 22, 2009

D. Device Name

Trade Name:	Trucath 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 Trucath Spinal Injection System is substantially equivalent to the Laurimed Spinal Injection System (K083909).

F. Device Description

The Trucath Spinal Injection System integrates a flexible Catheter with an atraumatic distal tip into a Needle designed for use in injections into the epidural space of the spine.

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

Intended Use

Indicated for use in injections into the epidural space. Not for use with other catheters or needles.

G. Technological Comparison

The technological characteristics and principals of operation of the Trucath 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 Trucath Spinal Injection System is safe and effective for its intended use.

I. Summary of Data

The Trucath 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 Trucath 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Sevrina Ciucci
Regulatory Affairs Consultant
Laurimed L.L.C.
500 Arguello Street, Suite 100
Redwood City, California 94063

SEP 23 2009

Re: K091818
Trade/Device Name: Trucath Spinal Injection System
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: August 24, 2009
Received: August 25, 2009

Dear Ms. Ciucci:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

for

Susan Runner, D.D.S., M.A.
Acting Division 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 K091818

Device Name: Trucath Spinal Injection System

Indications for Use:

The TruCath Spinal Injection System is indicated for use in injections into the epidural space. Not for use with other catheters or needles.

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)

L Schultz

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

510(k) Number: K091818