K082194

# 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
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**B. Contact Person**

Nancy Lincé
Clinical and Regulatory Affairs Consultant
(650) 759-6186

**C. Date Prepared**

August 1, 2008

**D. Device Name**

| | |
|---|---|
| Trade Name: | Laurimed Percutaneous Discectomy System |
| Common Name: | Tissue Cutter/Aspirator |
| Classification Name: | Arthroscope (21 CFR §888.1100, Product Code HRX) |

**E. Predicate Devices**

The Laurimed Percutaneous Discectomy System is substantially equivalent to Surgical Dynamics, Inc. *Nucleotome 3.5mm Automated Percutaneous Lumbar Discectomy Kit* (K923525) and *Nucleotome II (Version 2) Tissue Aspirator/Cutter* (K914282).

**F. Device Description**

The Laurimed Percutaneous Discectomy System is intended to be used to cut and aspirate nucleus material from discs in the spine. The system consists of a set of introduction tools (Introducer Needle with Stylet, Guidewire, Dilator, Cannula, Trocar, and Cannula Clamp), a Device Cleaner, and a Discectomy Device

The Laurimed Percutaneous Discectomy System is supplied as a sterile, single patient use, single-level, disposable device.

## G. Intended Use

The Laurimed Percutaneous Discectomy System is indicated for use in aspiration of disc material during percutaneous discectomies in the lumbar region of the spine.

## H. Technological Comparison

The technological characteristics and principals of operation of the Laurimed Percutaneous Discectomy System are substantially equivalent to the noted predicate devices.

## I. Summary of Non-Clinical Data

Results of non-clinical testing demonstrated that the Laurimed Percutaneous Discectomy System is safe and effective for its intended use.

## J. Summary of Data

The Laurimed Percutaneous Discectomy System has been carefully compared to legally marketed devices 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 Laurimed Percutaneous Discectomy System functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2008

Laurimed LLC
% Ms. Nancy Lincé
Clinical and Regulatory Affairs Consultant
500 Arguello Street, Suite 100
Redwood City, California 94063

Re: K082194
Trade/Device Name: Percutaneous Discectomy System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: August 1, 2008
Received: August 4, 2008

Dear Ms. Lincé:

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,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

**510(k) Number (if known):** K 082194

**Device Name:** Percutaneous Discectomy System

**Indications for Use:**

The Laurimed Percutaneous Discectomy System is indicated for use in aspiration of disc material during percutaneous discectomies in the lumbar region of the spine.

**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**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Mark A Melkerson

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K082194