

**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

MAY 21 2009

**B. Contact Person**

Sevrina Ciucci  
Regulatory Affairs Consultant  
(408) 316-4837

**C. Date Prepared**

March 20, 2009

**D. Device Name**

Trade Name: Laurimed Discectomy System  
Common Name: Tissue Cutter/Aspirator  
Classification Name: Arthroscope (21 CFR §888.1100) Product Code **H1RX1**

**E. Predicate Devices**

The Laurimed Discectomy System is substantially equivalent to the Laurimed *Percutaneous Discectomy System* (K082194).

**F. Device Description**

The Laurimed 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 (Dilator, Straight Cannula, Curved Cannula (qty. 2) and Trocar), a Device Cleaner, and a Discectomy Device

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

**G. Intended Use**

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

**H. Technological Comparison**

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

**I. Summary of Non-Clinical Data**

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

**J. Summary of Data**

The Laurimed Discectomy 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 Laurimed 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 device and is safe and effective for its intended use.



MAY 21 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K090815  
Trade/Device Name: Discectomy System  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: II  
Product Code: HRX  
Dated: March 20, 2009  
Received: March 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.

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.

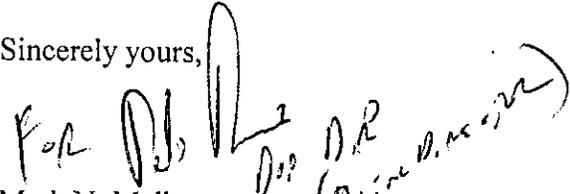
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

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(240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indication for Use Statement**

510(k) Number (if known): K 090815

Device Name: Discectomy System

**Indications for Use:**

The Laurimed Discectomy System is indicated for use in aspiration of disc material during open 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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. O'Brien, Sr. M.D.  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K090815