APR 15 2005

510(k) SUMMARY
InnoSpine, Inc.
Functional Anaesthetic Discography (FAD) System
510(k) Notification K043500

GENERAL INFORMATION

Applicant:
InnoSpine, Inc.
1766 Sand Hill Road, Unit 404
Palo Alto, CA 94304
Phone: 650-996-2110
FAX: 650-249-0218

Contact Person:
Laraine Pangelina
Regulatory Consultant
Experien Group, LLC
155 Moffett Park Drive, Suite A-101
Sunnyvale, CA 94089-1330
Phone: 408-400-0856
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Date Prepared:
December 17, 2004

DEVICE INFORMATION

The Functional Anaesthetic Discography (FAD) System consists of the FAD Catheter Kit and the FAD Introducer Needle.

Classification:
Class II, Anesthesia conduction catheter, 21 CFR §868.5120
Class II, Anesthesia conduction needle, 21 CFR §868.5150

Trade Name:
Functional Anaesthetic Discography (FAD) System:

- FAD Catheter Kit
- FAD Introducer Needle

Generic/Common Name:
Anesthesia conduction catheter
Anesthesia conduction needle

PREDICATE DEVICES

FAD Catheter Kit:
- Spinal Specialties Discography Kit, K960082, cleared 3/21/96
- Epimed Versa-Kath Epidural Catheter, K023140, cleared 8/15/03
- Braun Perifix Catheter, K042488, cleared 9/30/04

FAD Introducer Needle:
- Braun Perifix Safety Epidural Needle, K013610, cleared 1/25/02
- Epimed Quincke Spinal Needle, K022029, cleared 7/30/02
- Pajunk Touhy Needles, K040965, cleared 9/7/04

INTENDED USE

The Functional Anaesthetic Discography (FAD) System is intended for use in delivering either a single dose or continuous administration of radiopaque contrast, local anaesthetics, and/or saline solution to the intradiscal space. The FAD Introducer Needle is intended for use to access the area adjacent to the intradiscal space for the purpose of facilitating placement of the FAD Catheter and Guidewire into the intradiscal space.

PRODUCT DESCRIPTION

The Functional Anaesthetic Discography (FAD) System consists of the FAD Catheter Kit and the FAD Introducer Needle. The FAD Catheter Kit includes one FAD Catheter, one Guidewire, one FAD Introducer Needle, and other purchased accessories, including one spinal needle, one stopcock, one 3cc syringe, two 1cc syringes and two Touhy-Borst adapters.

The FAD Catheter is a micro-catheter with a flexible polymer shaft. There is a polymer anchor near the distal tip of the FAD Catheter, which is expanded once the catheter is in place for the purpose of maintaining proper catheter placement during the delivery of fluids into the intradiscal space. The anchor is contracted prior to removal of the catheter. Two lumens are contained inside the polymer shaft of the catheter, one for the purpose of expanding the anchor, the other for the purpose of tracking over the guidewire and injecting the desired fluid. There are two radiopaque markers, one proximal to the anchor and one distal to the anchor to allow for radiographic positioning of the anchor. There is also a nitinol guidewire, over which the catheter is tracked to the desired location.

The FAD Introducer Needle is provided in the FAD Catheter Kit and will also be sold separately. The FAD Introducer Needle is stainless steel and has a stainless steel stylet. The

FAD Introducer Needle provides access to the intradiscal space. The Guidewire and Catheter are delivered through the FAD Introducer Needle.

SUBSTANTIAL EQUIVALENCE:

The Functional Anaesthetic Discography (FAD) System consists of the FAD Catheter Kit and the FAD Introducer Needle.

FAD Catheter Kit:
The FAD Catheter Kit has substantially equivalent indications for use, and technological characteristics as the predicate devices which include:

- Spinal Specialties Discography Kit, K960082, cleared 3/21/96
- Epimed Versa-Kath Epidural Catheter, K023140, cleared 8/15/03
- Braun Perifix Catheter, K042488, cleared 9/30/04

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the FAD System. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the FAD Catheter Kit is substantially equivalent to the predicate devices.

FAD Introducer Needle:
The FAD Introducer Needle has substantially equivalent indications for use, and technological characteristics as the predicate devices which include:

- Braun Perifix Safety Epidural Needle, K013610, cleared 1/25/02
- Epimed Quincke Spinal Needle, K022029, cleared 7/30/02
- Pajunk Touhy Needles, K040965, cleared 9/7/04

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the FAD Introducer Needle. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the FAD Introducer Needle is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Any differences in technological characteristics between the FAD System and the predicate devices do not raise any new issues of safety or efficacy. The safety of the FAD System was evaluated through design verification testing, cadaver testing, and biocompatibility testing. The collective results have demonstrated that the FAD Catheter Kit and the FAD Introducer Needle are substantially equivalent to the respective predicate devices with regard to safety.

SUMMARY

The FAD Catheter Kit and the FAD Introducer Needle are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

InnoSpine, Incorporated
C/O Ms. Laraine Pangelina
Regulatory Consultant
Experien Group, LLC
11240 Magdalena Road
Los Altos Hills, California 94024

Re: K043500
Trade/Device Name: Functional Anaesthetic Discography (FAD) Catheter System
Regulation Number: 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: March 21, 2004
Received: March 24, 2005

Dear Ms. Pangelina:

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): **K043500**

Device Name: Functional Anaesthetic Discography (FAD) Catheter System

Indications for Use:

The Functional Anaesthetic Discography (FAD) Catheter System is intended for use in delivering either a single dose or continuous administration of a radiopaque contrast, local anaesthetics, and/or saline solution to the intradiscal space. The FAD Introducer Needle is intended for use to access the area adjacent to the intradiscal space for the purpose of facilitating placement of the FAD Catheter and Guidewire into the intradiscal space.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of [illegible] General Hospital,
Infection Control, Dental Devices
510(k) Number K043500

(Posted November 13, 2003)