Tab 4 K061210

JUN 27 2006

Premarket Notification [510(k)] Summary

Trade Name:	Functional Anaesthetic Discography (F.A.D.) Catheter System Functional Anaesthetic Discography (F.A.D.) Introducer Needle
Common Name:	Anesthesia conduction catheter Anesthesia conduction needle
Classification /Name:	Class II, Anesthesia conduction needle, 21 CFR 868.5150
Device Code:	BSP
Manufacturer's Name:	Kyphon Inc.
Address:	1221 Crossman Avenue Sunnyvale, CA 94089
Corresponding Official:	Cindy Domecus
Title:	Vice President, Clinical Research and Regulatory Affairs
Address:	1221 Crossman Avenue Sunnyvale, CA 94089
Phone:	(408) 548-5421
Predicate Device(s):	K043500, Functional Anaesthetic Discography (F.A.D.) Catheter System, cleared on April 15, 2005.
Intended Use:	The **Functional Anaesthetic Discography (F.A.D.) 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 **Functional Anaesthetic Discography (F.A.D.) Introducer Needle** is intended for use to access the area adjacent to the intradiscal space for the purpose of facilitating placement of the F.A.D. Catheter and Guidewire into the intradiscal space.

Any statement regarding "substantial equivalence" made in this submission only relates to whether the product addressed in this submission may be lawfully marketed without premarket approval or reclassification, and is not intended to be interpreted as an admission or any other type of evidence in any patent proceeding, including patent infringement litigation or proceeding before any Patent Office. The present submission and statements therein therefore should not be construed as affecting or relating to the scope of any patent or patent application, or to whether the product addressed in this submission, or its use, may be considered indistinct, from a patentability perspective, from any of the other devices referenced in this filing.

Device Description: The F.A.D. Catheter is a micro-catheter with a flexible shaft. The F.A.D. Catheter has a polymer balloon located near the distal tip. Once the F.A.D. Catheter is properly positioned, the balloon is inflated with a radiopaque contrast medium and assists in maintaining proper catheter placement during the procedure. The balloon is then deflated prior to removal of the F.A.D. Catheter. Two stainless steel tubes are contained inside the polymer shaft of the F.A.D. Catheter and serve as lumena. The inflation lumen is used for inflating and deflating the balloon and the guidewire / injection lumen is used for insertion of a guidewire and injection of radiopaque contrast, local anaesthetics, and/or saline solution. The proximal portion of both lumena are connected to the Portex® Epidural Catheter Connector Adapters during the procedure. There are two radiopaque markers on the F.A.D. catheter shaft, located proximally and distally within the balloon, allowing for radiographic positioning of the balloon. There are eight markers on the proximal end of the catheter which can be utilized to monitor stable catheter placement during the course of the procedure.

The F.A.D. Introducer Needle is designed specifically for use with the F.A.D. Catheter System. The F.A.D. Introducer Needle is manufactured from stainless steel and has a stainless steel stylet. The F.A.D. Introducer Needle has a square cut distal tip with rounded edges. The stylet has a bevel tip. The F.A.D. Introducer Needle provides access to the area adjacent to the intradiscal space. The F.A.D. Catheter is delivered through the F.A.D. Introducer Needle and is tracked over the guidewire.

The F.A.D. Catheter System is comprised of the following:

- One F.A.D. Catheter
- One F.A.D. Introducer Needle
- One Spinal Needle
- One Guidewire
- One Stopcock
- One 3cc syringe
- Two 1cc syringes
- Two Catheter Connectors (toughy-borst adapters)
- One package of sterile labels

The F.A.D. Introducer Needle is also offered a la carte.

Substantial Equivalence:

This 510(k) is being filed for the addition of labeling information in the Instructions for Use of Kyphon's Functional Anaesthetic Discography (F.A.D.) Catheter System and Functional Anaesthetic Discography (F.A.D.) Introducer Needle. Both devices are already cleared for use under 510(k) #K043500. The additional contraindication, warnings, and adverse events noted in this submission do not represent a change to either device's intended use or indications for use. There are also no changes to the primary design elements for either device that are the subject of this submission. Therefore, devices and the device labeling are substantially equivalent to the devices already cleared under K043500.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2006

Ms. Cindy Domecus
Vice President
Kyphon, Incorporated
Clinical Research and Regulatory Affairs
1221 Crossman Avenue
Sunnyvale, California 94089

Re: K061210
Trade/Device Name: Functional Anaesthetic Discography (FAD) Catheter
Regulation Number: 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: June 5, 2006
Received: June 6, 2006

Dear Ms. Domecus:

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): K061210

Device Name: Functional Anaesthetic Discography (FAD) Catheter System &

Functional Anaesthetic Discography (FAD) Introducer Needle

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 **Functional Anaesthetic Discography (FAD) Introducer** 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 (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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...t of Anaesthesiology, General Hospital
...ion Control, Dental Devices
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