APR 13 2007

Premarket Notification [510(k)] Summary

Trade Name:	Discyphor™ Catheter System Discyphor™ Introducer Needle Discyphor™ Spinal 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:	Clinical Research and Regulatory Affairs Consultant
Address:	1221 Crossman Avenue Sunnyvale, CA 94089
Phone:	(408) 548-5421
Predicate Device(s):	K061210, Functional Anaesthetic Discography (F.A.D.) Catheter System, cleared on June 27, 2006. K043500, Functional Anaesthetic Discography (F.A.D.) Catheter System, cleared on April 15, 2005.

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.

Intended Use:

The **Kyphon Discyphor Catheter System** for the Functional Anaesthetic Discography Procedure, and its components, are 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 **Discyphor Introducer Needle** is intended for use to access the area adjacent to the intradiscal space for the purpose of facilitating sequential placement of the Discyphor Spinal Needle, Discyphor Catheter and Discyphor Guidewire into the intradiscal space. The Kyphon Discyphor Introducer Needle is intended to be used only with the Kyphon Discyphor Catheter System.

The **Kyphon Discyphor Spinal Needle** is intended to access the nucleus of an intervertebral disc for the purpose of performing provocative discography and facilitating placement of the Discyphor Catheter and Guidewire into the intradiscal space. The Discyphor Spinal Needle can be used to deliver contrast, antibiotic, and/or saline into an intervertebral disc. The Kyphon Discyphor Spinal Needle is intended to be used only with the Kyphon Discyphor Catheter System.

Device Description:

The Discyphor™ Catheter System is comprised of a Discyphor™ Catheter with guidewire funnel, a Discyphor™ Guidewire, a Discyphor™ Introducer Needle, a Discyphor™ Spinal Needle, a stopcock, syringes, catheter connectors and labels. The Discyphor Catheter is a micro-catheter with a flexible shaft and a balloon located near the distal tip. The metallic Discyphor Guidewire is .009" in diameter and is radiopaque when viewed using fluoroscopy. The stopcock retains pressure within the balloon when used in conjunction with the syringes. The catheter connectors are connected to the lumens of the Discyphor Catheter and provide access to the lumens. Labels are used to identify the solutions used during the procedure or to denote the level at which the Discyphor Catheter has been placed.

The Discyphor Introducer Needle is designed specifically for use with the Discyphor Catheter System. The Discyphor Introducer Needle is stainless steel with a removable stainless steel stylet. The Discyphor Catheter is delivered through the Discyphor Introducer Needle and is tracked over the Discyphor Guidewire.

The Discyphor™ Spinal Needle is a standard stainless steel needle with a removable stainless steel stylet. The hubs of the needle and stylet are comprised of polymer.

Substantial Equivalence:

This 510(k) describes a material change to the Discyphor Guidewire. The Discyphor Guidewire is one component of the Discyphor Catheter System.

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.

The guidewire materials for the Discyphor Guidewire include Nitinol and Elgiloy. *In vitro* testing was conducted on the materials to evaluate bending stiffness, peak axial strength, fracture and kink resistance. In addition laboratory physician preference testing was conducted. Biocompatibility testing conducted on the Discyphor Catheter System and Guidewire assembly demonstrates that the materials are acceptable for the intended use. The results of testing demonstrate that the guidewire materials are safe and effective for the intended use. The changes described in this submission do not represent a change to the intended use and they do not represent a change in the fundamental scientific technology of the device. Therefore, the devices included in this submission are substantially equivalent to the predicate devices already cleared under K061210.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2007

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

Re: K063071
Trade/Device Name: Discyphor™ Catheter System, Discyphor™ Introducer Needle, Discyphor™ Spinal Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: March 14, 2007
Received: March 15, 2007

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.

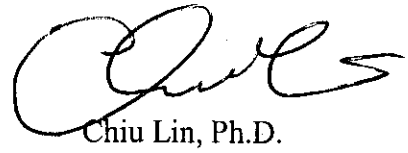
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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): K063071

Device Name: Discyphor™ Catheter System
Discyphor™ Introducer Needle
Discyphor™ Spinal Needle

Indications for Use:

The **Kyphon Discyphor Catheter System** for the Functional Anaesthetic Discography™ Procedure, and its components, are 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 **Kyphon Discyphor Introducer Needle** is intended for use to access the area adjacent to the intradiscal space for the purpose of facilitating sequential placement of the Discyphor Spinal Needle, Discyphor Catheter and Discyphor Guidewire into the intradiscal space. The Kyphon Discyphor Introducer Needle is intended to be used only with the Kyphon Discyphor Catheter System.

The **Kyphon Discyphor Spinal Needle** is intended to access the nucleus of an intervertebral disc for the purpose of performing provocative discography and facilitating placement of the Discyphor Catheter and Guidewire into the intradiscal space. The Discyphor Spinal Needle can be used to deliver contrast, antibiotic, and/or saline into an intervertebral disc. The Kyphon Discyphor Spinal Needle is intended to be used only with the Kyphon Discyphor Catheter System.

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)

Page 1 of 1

...ion of Ane... General Hospital,
...ion Control, Dental Devices

...(k) Number K063071