K073516

Tab 5
PREMARKET NOTIFICATION [510(k)] SUMMARY

Trade Name:	Kyphon Discyphor Direct™ Catheter System Kyphon Discyphor Direct™ Outer Needle Kyphon Discyphor Direct™ Inner 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:	Pamela Segale
Title:	Director, Regulatory Affairs
Address:	1221 Crossman Avenue Sunnyvale, CA 94089
Phone:	(408) 548-5235
Predicate Device(s):	K063071 (cleared on April 13, 2007): Discyphor™ Catheter System Discyphor™ Introducer Needle Discyphor™ Spinal Needle

K061210, (cleared on June 27, 2006) Functional Anaesthetic Discography (F.A.D.) Catheter System.

K043500, (cleared on April 15, 2005) Functional Anaesthetic Discography (F.A.D.) Catheter System.

The **Kyphon Discyphor Direct™ 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.

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 **Kyphon Discyphor Direct™ Outer Needle** is intended for use to access the area adjacent to the intradiscal space for the purpose of facilitating sequential placement of the Discyphor Direct™ Inner Needle and Discyphor Direct™ Catheter into the intradiscal space. The Discyphor Direct ™Outer Needle is intended to be used only with the Discyphor Direct™ Catheter System.

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

Device Description:

The Discyphor Direct™ Catheter System is comprised of a Discyphor Direct™ Catheter, a Balloon Inflation Assembly, a Stopcock Assembly, an Injection Assembly, an EPI-Guard Catheter Anchoring Device, Adhesive Clips, a Sheet of Labels, 1-cc Syringes and a Discyphor Direct™ Outer Needle (with stylet) and a Discyphor Direct™ Inner Needle (with stylet).
The Discyphor Direct™ Catheter is a micro-catheter with a double lumen shaft and an inflatable balloon at its distal end.

The Balloon Inflation Assembly, a Stopcock Assembly, an Injection Assembly are intended to be connected to the lumens of the catheter and to provide access to the lumens. The Balloon Inflation Assembly consists of an a 3-cc Syringe and a pressure relief valve. The Stopcock Assembly consists of a Stopcock, a Touhy Borst adapter and a Wing Nut. The Injection Assembly consists of a Touhy Borst adapter, a One-way valve and a Wing Nut. The EPI-Guard Catheter Anchoring Devices secures the catheter close to the needle puncture site. The Adhesive Clips are used to secure the catheter to the patient.

The 1-cc Syringes can be used for injection of contrast, antibiotic, and/or saline into the disc space.

The labels provided on the Label Sheet 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 Direct™ Outer Needle is manufactured from stainless steel and has a stainless steel stylet with a beveled tip and a polycarbonate wing.

The Discyphor Direct™ Inner Needle is manufactured from stainless steel and has a stainless steel stylet.

Testing

Testing of the Discyphor Direct™ Catheter System and the Discyphor Direct™ Needles was completed to demonstrate that the devices meet the specifications and performance characteristics, and were substantially equivalent to the predicate devices. This included dimensional verification, tensile testing, bending stiffnes, corrosion verification, fatigue testing, functional testing and testing of the handling. In addition, biocompatibility testing and sterilization validation were completed.

Sterilization

The Discyphor Direct™ Catheter System and the Discyphor Direct™ Outer and Inner Needles will be provided sterile and are intended for single use only.

Packaging and Labeling

The Discyphor Direct™ Catheter System is packaged in a Tyvek® sealed PETG tray and a cardboard box. The 1-cc syringes are packaged separately in Tyvek® pouches and are provided with the Discyphor Direct™ Catheter System package. The Discyphor Direct™ Outer and Inner Needles are packaged separately in Tyvek® pouches and are provided in a cardboard box.

Substantial Equivalence:

The information submitted in this pre-market notification supports a determination that the Discyphor Direct™ Catheter System and Discyphor Direct™ Outer and Inner Needles are substantially equivalent to the predicate devices cleared under K063071. The results of testing demonstrate that the Discyphor Direct™ Catheter System and Discyphor Direct™ Outer and Inner Needles are safe and effective for their intended uses. The changes described in this submission do not represent a change to the intended usees 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 K063071.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Ms. Pamela Segale
Director, Regulatory Affairs
Kyphon, Incorporated
1221 Crossman Avenue
Sunnyvale, California 94089

Re: K073516
Trade/Device Name: Kyphon Discyphor™ Catheter System
Kyphon Discyphor™ Outer Needle
Kyphon Discyphor™ Inner Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II
Product Code: BSP
Dated: December 13, 2007
Received: December 14, 2007

Dear Ms. Segale:

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 STATEMENT

510(k) Number (if known): K073516

Device Name: Kyphon Discyphor Direct™ Catheter System
Kyphon Discyphor Direct™ Outer Needle
Kyphon Discyphor Direct™ Inner Needle

Indications for Use:

The **Kyphon Discyphor Direct™ 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 Direct™ Outer Needle** is intended for use to access the area adjacent to the intradiscal space for the purpose of facilitating sequential placement of the Discyphor Direct™ Inner Needle and Discyphor Direct™ Catheter into the intradiscal space. The Discyphor Direct™ Outer Needle is intended to be used only with the Discyphor Direct™ Catheter System.

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073516