



APR. 13. 2007 2:33PM

FAD-CDRH-ODE-DAGID

DEPARTMENT OF HEALTH & HUMAN SERVICES

NO. 0762 P. 2
Public Health Service

APR 13 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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.

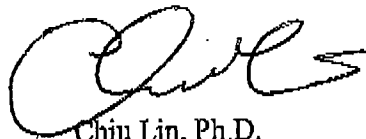
Page 2 – Ms. Domecus

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" (21 CFR 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 AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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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Division of Anesthesiology, General Hospital,
Regulation Control, Dental Devices

510(k) Number K063071

**DHHS/PHS/FDA/CDRH
DIVISION OF ANESTHESIOLOGY,
GENERAL HOSPITAL, INFECTION CONTROL
AND DENTAL DEVICES
9200 CORPORATE BOULEVARD
HFZ-480
ROCKVILLE, MARYLAND 20850**



DATE: 4/13/07
FROM: Kimberly Love
TO: Ms. Cindy Domecus
PHONE #: _____
FAX #: 408-222-6715
SUBJECT: K063071

ADDITIONAL COMMENTS: _____

OF PAGES & COVER SHEET: _____

PHONE NO: (240) 276-3700

FAX NO: (240) 276-3789

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