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