DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2005

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

Re: K032212
Trade/Device Name: KyphX™ Directional Inflatable Bone Tamps
Regulation Number: 21CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: July 16, 2003
Received: July 21, 2003

Dear Ms. Domecus:

This letter corrects our substantially equivalent letter of September 15, 2003.

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 (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.

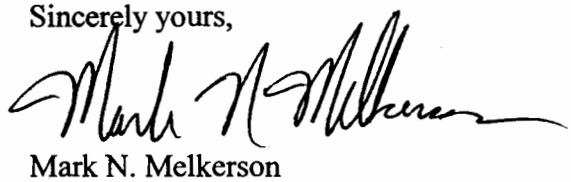
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Tab 4

Indications For Use

510(k) Number: K032212

Device Name: KyphX® Directional Inflatable Bone Tamps

Indications for Use:

KyphX® Directional Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius and calcaneous.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Melkerson
Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032212

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)

K032212

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Tab 5

Premarket Notification [510(k)] Summary

July 16, 2003

Trade Name: **Kyphx Directional Inflatable Bone Tamps**

Common Name: Inflatable Bone Tamp

Classification /Name: Class II

Tamp: HXG; 21 CFR section 888.4540
Arthroscope: HRX; 21 CFR section 888.1100

Manufacturer's Name: Kyphon Inc.
Address: 1350 Bordeaux Drive
Sunnyvale, CA 94089

Corresponding Official: Tim Reeves
Regulatory Affairs Manager
Address: 1350 Bordeaux Drive
Sunnyvale, CA 94089
Telephone: 408-548-6500

Predicate Device(s): KyphX Inflatable Bone Tamp, K010246
Kyphon Inflatable Bone Tamp, K981251

Device Description: The KyphX Directional Inflatable Bone Tamps (IBTs) are designed to compress cancellous bone and/or move cortical bone as they inflate. The inflatable component of the IBT is near the distal tip of the device. The catheter shaft contains an outer lumen for IBT inflation and a central lumen for a stylet to facilitate catheter introduction. At full inflation volume, the balloon design allows directionality of inflation with a maximum inflated diameter that is perpendicular to the catheter shaft. One design has a uniform balloon that is concentric to the catheter shaft. Another design has a non-uniform balloon that is tangential to the catheter shaft. Directionality of the balloon is indicated by external markers on the proximal Y-adapter component. Each design enables fluoroscopic visualization of the deflated balloon.

Intended Use: KyphX Directional Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius and calcaneous.

Sterilization: The KyphX Directional Inflatable Bone Tamps are sterilized using gamma radiation and meet the requirement of ANSI/AAMI/ISO11137 for gamma-sterilized devices.

Mechanical Tests: Mechanical testing of the KyphX Directional Inflatable Bone Tamps verifies the devices meet the performance specifications of the IBT predicates.

Biocompatibility: The materials used in the construction of the KyphX Directional Inflatable Bone Tamps meet the requirements for "Externally Communicating Devices, Tissue/Dentin/Bone, Limited Contact" described in the FDA Blue Book Memorandum #G95-1, "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".

Substantial Equivalence: The KyphX Directional Inflatable Bone Tamps meet the physical and performance specifications established for the IBT predicates. The products have the same fundamental scientific technology and intended use as the IBT predicates. The information submitted in this pre-market notification support a determination that the KyphX Directional Inflatable Bone Tamps are substantially equivalent to the IBT predicates.

As with Kyphon's cleared Kyphon and KyphX™ Inflatable Bone Tamp 510(k)s, K981251 and K102046, any statement regarding "substantial equivalence" made in this submission only relates to whether the product can 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 patent infringement litigation. The present submission is therefore not related to the coverage of any patent or whether these products or their uses may be considered distinct from a patent point of view.