



SEP 30 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K981251
Trade/Device Name: Kyphon Inflatable Bone Tamp
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: April 3, 1998
Received: April 6, 1998

Dear Ms. Domecus:

This letter corrects our substantially equivalent letter of July 2, 1998, regarding the regulation number for your device.

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.

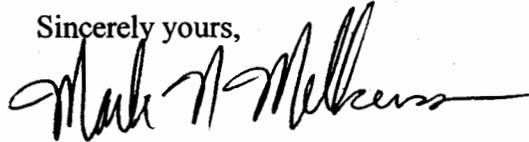
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

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

510(k) Number (if known): K981251

Device Name: Kyphon Inflatable Bone Tamp

Indications For Use:

Kyphon Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction for fractures and/or creation of a void in cancellous bone.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Handwritten Signature]

K981251

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K981251

Prescription Use X
(Per 21 CFR 201.109)

OR

Over-The-Counter Use

JUL - 2 1998

K981251

**510(k) Summary of Safety and Effectiveness
Kyphon Inflatable Bone Tamp**

This 510(k) safety and effectiveness summary is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 and 21 CFR §807.92.

General Information

Manufacturer: Kyphon Inc.
3110 Coronado Dr.
Santa Clara, CA 95054

Contact Person: Karen Talmadge, Ph.D.
President

Date Prepared: 29 June 1998

Device Information

Classification: Class II
Trade Name: Kyphon Inflatable Bone Tamp
Common Name: Tamp

Intended Use

Kyphon 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.

Product Description

The Kyphon Inflatable Bone Tamp is a bone tamp with an inflatable component at the distal end. It is designed to compress cancellous bone and/or move cortical bone as it inflates. The Inflatable Bone Tamp has a nominal length of 40 cm and consists of a double lumen catheter shaft constructed from two coaxially aligned tubings. The inflatable component is mounted near the distal tip of the catheter tubing. Two radiopaque marker bands are attached to the inner tubing and located at the proximal and distal ends of the inflatable component.

A side arm adapter attached to the proximal end of the Inflatable Bone Tamp provides access to the catheter lumens. Inflation and deflation are accomplished by connecting the side arm port with an inflation syringe. The straight arm port is continuous with the inner lumen of the catheter to allow placement of a removable stiffening stylet, which attaches to the Luer fitting of the straight arm.

Substantial Equivalence

The Kyphon Inflatable Bone Tamp is substantially equivalent to currently marketed bone tamps, elevators and curettes (Class I) with regard to intended use, function and biomechanical performance. With regard to technological characteristics such as materials, construction and mode of performance (inflatable component), the Inflatable Bone Tamp is substantially equivalent to inflatable dissectors, such as the GSI Surgical Dissector (Class II). For percutaneous use, the Inflatable Bone Tamp is substantially equivalent to endoscopic devices, such as the Koros Microdissectomy Curette (Class II).

Biocompatibility Evaluations

The materials used in the construction of the Kyphon Inflatable Bone Tamp meet the requirements for “Externally Communicating Devices, Tissue/Dentin/Bone, Limited Contact” as described in the FDA Blue Book Memorandum #G95-1 entitled, “Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”. The biocompatibility tests demonstrate that this device is biocompatible.

Sterilization

The Kyphon Inflatable Bone Tamp is sterilized using ethylene oxide (EtO) and meets the requirements of ANSI/AAMI/ISO11135:1994 for EtO sterilized devices.

Mechanical and Pre-Clinical Tests Performed

Mechanical tests performed for the Inflatable Bone Tamp to verify the device meets specifications and intended performance characteristics include:

- Maximum Inflation Volume
- Inflated Length
- Inflated Diameter
- Fatigue Performance
- Maximum Recommended Inflation Pressure
- Overall Length
- Working Length
- Shaft Diameter
- Inflation Time
- Deflation Time
- Tamp Insertion Force
- Tamp Withdrawal Force
- Bond Strength - Outer Tubing to Side Arm
- Bond Strength - Inner Tubing to Luer
- Bond Strength - Luer to Y-Adapter
- Biocompatibility Testing

Results from all tests demonstrated the Inflatable Bone Tamp performed according to design specifications.

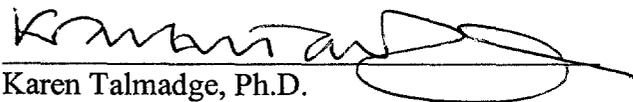
Pre-clinical testing was conducted to verify that the Kyphon Inflatable Bone Tamp performs according to its design specification and to validate substantial equivalence to the performance of conventional bone tamps. Tests of intended use, performance to specification and safety were conducted in isolated, fractured, cadaveric vertebral bodies. Tests of percutaneous deployment and intended use were performed in fractured tibial plateaus in cadaver knees and in unfractured vertebral bodies in cadaver spines.

The results of these tests demonstrated that Kyphon Inflatable Bone Tamps can reduce fractures, and create voids in cancellous bone, in the same manner and with the same results as predicate conventional bone tamps. These tests also showed product performance in bone conformed to design specifications. Safety testing demonstrated that the risks of tamping with Inflatable Bone Tamps are the same as those of conventional bone tamps, and that the risks of product failure are the same as those of inflatable dissectors and other inflatable medial products.

Kyphon Inc. has determined, based on these tests, that the device conforms to its specifications and is at least as safe and effective as the predicate devices for tamping cancellous bone and/or elevating cortical bone.

Summary

In summary, the Kyphon Inflatable Bone Tamp meets design specifications and performs like conventional bone tamps, elevators and curettes for the reduction of fractures and creation of voids in cancellous bone. The Inflatable Bone Tamp is constructed from similar materials as surgical dissectors and performs using hand pressure (via hydraulic inflation). Design features similar to those in other endoscopic products allow the Kyphon Inflatable Bone Tamp to be used percutaneously. The Kyphon Inflatable Bone Tamp does not raise any new questions of safety or effectiveness.



Karen Talmadge, Ph.D.

President

Kyphon Inc.

29 June 1998