



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated  
Ms. Pamela Edwards  
Principal Regulatory Affairs Specialist  
1800 Pyramid Place  
Memphis, Tennessee 38132

July 23, 2015

Re: K151532

Trade/Device Name: KYPHON ELEMENT™ Inflatable Bone Tamp  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: Class II  
Product Code: HRX, HXG  
Dated: June 9, 2015  
Received: June 10, 2015

Dear Ms. Edwards:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joshua C. Nipper -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151532

Device Name

KYPHON ELEMENT™ Inflatable Bone Tamp

Indications for Use (Describe)

The KYPHON ELEMENT™ Inflatable Bone Tamp (IBT) is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during a balloon kyphoplasty procedure with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(K) Summary

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**I. SUBMITTER NAME & ADDRESS:** Medtronic Sofamor Danek USA, Inc  
 1800 Pyramid Place  
 Memphis, Tennessee 38132  
 Telephone: (901) 396-3133  
 Fax: (901) 346-9738  
 Establishment Registration: 1030489

**CONTACT PERSON:** Pamela Edwards  
 Principal Regulatory Affairs Specialist

**DATE PREPARED:** June 5, 2015

**II. PROPOSED PROPRIETARY TRADE NAME:** KYPHON ELEMENT™ Inflatable Bone Tamp

**DEVICE CLASSIFICATION NAME/** Arthroscope (21 CFR 888.1100)  
 Orthopedic Manual Surgical Instrument

**REGULATION NUMBER:** (21 CFR 888.4540)

**PRODUCT CODE:** HRX, HXG

**CLASSIFICATION:** II

### III. IDENTIFICATION OF LEGALLY MARKETED DEVICES:

Table 1. Legally Marketed Devices		
Device name	510(k) number	Substantial Equivalence date
KYPHON® XPANDER® Inflatable Bone Tamps	K041454	07/09/2004

### IV. DEVICE DESCRIPTION:

The KYPHON ELEMENT™ Inflatable Bone Tamp is designed for the reduction of fractures. The main components are a single lumen shaft, Y-Adapter with a port to connect the inflation syringe for inflation/deflation, and the inflatable balloon located at the distal tip.

### V. INDICATIONS FOR USE:

The KYPHON ELEMENT™ Inflatable Bone Tamp (IBT) is intended to be used as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during a balloon kyphoplasty procedure with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures), hand, tibia, radius, and calcaneus.

#### **VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS:**

The subject KYPHON ELEMENT™ Inflatable Bone Tamp has the same intended use, fundamental scientific technology, and sterilization as the predicate KYPHON® XPANDER® Inflatable Bone Tamps K041454 (S.E. 07/09/2004). The subject utilizes equivalent basic device design, materials and packaging.

#### **VII. DISCUSSION OF NON-CLINICAL TESTING:**

Assessment of the device modifications have been completed in accordance with Medtronic design control processes. The KYPHON ELEMENT™ Inflatable Bone Tamp has the same design characteristics, packaging, sterilization processes and is made of equivalent materials as the predicate, KYPHON® XPANDER® Inflatable Bone Tamps. Mechanical testing, biocompatibility testing and other verification/validation activities were conducted to confirm that the modified device functions as intended and does not raise any new issues of safety or effectiveness.

#### **VIII. CONCLUSION:**

Documentation provided in this submission demonstrates that the subject device KYPHON ELEMENT™ Inflatable Bone Tamp is substantially equivalent to the previously cleared KYPHON® XPANDER® Inflatable Bone Tamps K041454 (S.E. 07/09/2004). The subject device is substantially equivalent to predicate in several categories including: intended use, performance specifications and fundamental technological characteristics.