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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

APR 23 2008

General Company Information

Name:	Tornier, Inc.
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Date Prepared	February 6, 2008

General Device Information

Product Name:	CINCH™ Knotless Fixation Implant System
Classification:	"Non-degradable soft tissue fixation fastener" Product code: MBI - Class II

Predicate Device

C2M Medical, Inc.	CINCH™ Knotless Fixation Implant System. [510(k) Number K073226]
ArthroCare Corp.	Opus® Magnum™ PI Knotless Fixation Device [510(k) K070227]
Arthrex, Inc.	Arthrex Corkscrew FT [510(K) K0061665]
Mitek Products	Mini QuickAnchor® Plus [510(K) K002487]

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Description

The CINCH™ Knotless Fixation Implant System includes a 3.5 mm diameter bone anchor and a disposable preloaded anchor Inserter. The CINCH™ Knotless Fixation Implant is designed to secure soft tissue to bone using USP #2 high strength non-absorbable UHMWPE braided suture. The CINCH™ system includes a Suture Loading Assembly that is attached to the distal end of the Inserter Handle. The CINCH™ Bone Anchor is a knotless fixation device eliminating the need for surgical knots. The device is designed for inserting the implant directly into bone without a pre-drilled, punched, or tapped pilot hole.

The CINCH™ Anchor configuration is comprised of a curved nitinol base, a flared nitinol clip, two titanium rings and a titanium cross pin. The CINCH™ Anchor is 12.9 mm long from rings to tip and 3.5 mm in diameter prior to wing deployment and 7.4 mm wide with wings expanded.

Intended Use (Indications)

The Tornier CINCH™ Knotless Fixation Implant is intended for fixation of soft tissue to bone.

The CINCH™ Implant is intended for use in the following applications:

- **Shoulder:** Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulabral Reconstruction
- **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair
- **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair. Illiotibial Band Tenodesis
- **Hand/Wrist:** Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
- **Elbow:** Biceps Tendon Reattachment, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
- **Pelvis:** Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency

Substantial Equivalence

This submission supports the position that the Tornier CINCH™ Knotless Fixation Implant System is substantially equivalent to a number of pre-enactment and previously cleared devices, including those listed above. A number of the referenced predicate devices list the same range of clinical uses.

Conclusions

Tornier, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the Tornier CINCH™ Knotless Fixation Implant System. The materials from which the Tornier device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 2008

Tornier, Inc.
c/o Mr. Howard Schrayer
100 Cummings Center
Suite 444C
Beverly, MA 01915

Re: K080335
Trade/Device Name: Tornier, CINCH™ Knotless Fixation Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 6, 2008
Received: February 7, 2008

Dear Mr. Schrayer:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

Enclosure

K080335

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Tornier, CINCH™ Knotless Fixation Implant System

Indications For Use:

The Tornier CINCH™ Knotless Fixation Implant is intended for fixation of soft tissue to bone.

The CINCH™ Implant is intended for use in the following applications:
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulabral Reconstruction
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Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair. Illiotibial Band Tenodesis
Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Elbow: Biceps Tendon Reattachment, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency

Prescription Use ____X_____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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