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# 510(K) SUMMARY

ARTHROCARE CORPORATION
OPUS MAGNUM KNOTLESS FIXATION DEVICES

JAN 12 2009

## General Information

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| **Submitter Name/Address:** | ArthroCare Corporation<br>680 Vaqueros Avenue<br>Sunnyvale, CA 94085-3523 |
| **Establishment Registration No.:** | 2951580 |
| **Contact Person:** | Laura N. Kasperowicz<br>Sr. Manager, Regulatory Affairs |
| **Date Prepared:** | October 31, 2008 |

## Device Description

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| **Trade Name:** | Opus Magnum2® Knotless Fixation Device<br>Opus Magnum X® Knotless Fixation Device |
| **Generic/Common Name:** | Bone Anchor |
| **Classification Name:** | Screw, Fixation, Bone<br>(Class II per 21 CFR 888.3040, Product code: MBI) |

## Predicate Devices

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| Opus Magnum PI | K070227 (Cleared 04/16/07) |
| Opus MiniMagnum | K042584 (Cleared 12/14/04) |

## Product Description

The Opus Magnum2 and the Opus Magnum X devices are bone anchor systems with inserter handles designed for specific indications in arthroscopic and orthopedic procedures.

## Indications For Use

The Opus Magnum2 and the Opus Magnum X devices are bone anchor systems with inserters that are indicated for use in fixation of soft tissue to bone. Examples of such procedures include:

**Shoulder:** Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis and deltoid repair

**Ankle:** Lateral instability, medial instability, Achilles tendon repair/reconstruction and midfoot reconstruction

**Foot:** Hallux valgus reconstruction

**Elbow:** Tennis elbow repair, biceps tendon attachment

**Knee:** Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

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# 510(K) SUMMARY

**Substantial Equivalence**

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate devices. The Opus Magnum2 and Opus Magnum X design and technology is substantially equivalent to the existing Opus MiniMagnum and Opus Magnum PI Knotless Fixation Devices cleared by the Food & Drug Administration (K042584 and K070227 respectively). The differences between the Opus Magnum2 and the Opus Magnum X, and the predicate devices do not raise any questions regarding the safety and effectiveness of the implants. Furthermore, the materials are well characterized and have been used in predicate devices with similar indications. The devices, as designed, are as safe and effective as predicate devices.

**Summary and Reason for 510k Notification**

The purpose of this 510k is to notify the Food and Drug Administration of expanded indications for use of existing products, the Opus Magnum2 and Opus Magnum X Knotless Fixation Devices. The expanded indications for use of these existing products are substantially equivalent to those for the Opus MiniMagnum Knotless Fixation Device originally cleared under K042584, and the Opus Magnum PI Knotless Fixation Device originally cleared under K070227.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2009

ArthroCare Corporation
% Ms. Laura N. Kasperowicz
15285 Alton Parkway, Suite 200
Irvine, CA 92618

Re: K083240
Trade/Device Name: Opus Magnum2 and Magnum X Knotless Fixation Devices
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: October 31, 2008
Received: November 3, 2008

Dear Ms. Kasperowicz:

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 toll-free number (800) 638-2041 or (240) 276-3150 or the 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

# INDICATIONS FOR USE STATEMENT

510(k) Number: K083240

Device Name: Opus Magnum2® and Opus Magnum X® Knotless Fixation Devices

Indications for Use:

The Opus Magnum2 and Opus Magnum X bone anchors with inserters are indicated for use in fixation of soft tissue to bone. Examples of such procedures include:
**Shoulder:** Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis and deltoid repair
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| Prescription Use (Part 21 CFR 801 Subpart D) | X | AND/OR | Over-The-Counter Use (21 CFR 801 Subpart C) | NO |

(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 General, Restorative, and Neurological Devices

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