DEC 07 2007

510(k) Summary

Trade Name: CINCH™ Knotless Fixation Implant System

Sponsor:
C2M Medical, Inc.
3463 Magic Drive, Suite 320
San Antonio, Texas 78229
Telephone: 1-877-300-5010
Fax: 1-210-582-5811
Contact Person: Gabriele G. Niederauer, Ph.D.

Date of Summary: November 13, 2007

Device Classification Name:
21 CFR §888.3040
Fastener, fixation, nondegradable, soft tissue

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices:
Original CINCH™ Bone Anchor System
DePuy/Mitek Rotator Cuff QuickAnchor® Plus

Device Description: The CINCH™ Knotless Fixation Implant includes single-use, sterile Anchor (3.5mm in diameter), which is preloaded onto a disposable anchor inserters.

Purpose of the Special 510(k) notice: The CINCH™ Knotless Fixation Implant System is a modification to the original CINCH™ Bone Anchor System

Indications for Use: The CINCH™ Knotless Fixation Implant System is intended to be used for fixation of soft tissue to bone during rotator cuff repair.

Safety and Performance: Results of bench testing demonstrate that the CINCH™ Knotless Fixation Implant System meets its specifications and does not raise new issues of safety or effectiveness. In all instances, the CINCH™ Knotless Fixation Implant functioned as intended.

Technological Characteristics

The CINCH™ Knotless Fixation Implant System is comprised of nondegradable suture anchors each pre-loaded onto an inserter.

Substantial Equivalence

The modified CINCH™ Knotless Fixation Implant System is substantially equivalent to the original CINCH™ Bone Anchor System and DePuy/Mitek Products' Rotator Cuff QuickAnchor® Plus. The CINCH™ Knotless Fixation Implant System has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the CINCH™ Knotless Fixation Implant System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the CINCH™ Knotless Fixation Implant System is as safe and effective as the predicate devices. Thus, the CINCH™ Knotless Fixation Implant System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 07 2007

C2M Medical, Inc.
% Gabriele G. Niederauer, Ph.D.
Vice President, Research and Development
3463 Magic Drive, Suite 320
San Antonio, Texas 78229

Re: K073226
Trade/Device Name: CINCH™ Knotless Fixation Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: November 14, 2007
Received: November 15, 2007

Dear Dr. Niederauer:

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

M. Attachment 13 - Indications for Use Statement

Indications for Use Statement

510(k) Number (if known): K073226

Device Name: CINCH™ Knotless Fixation Implant System

Indications for Use:

The CINCH™ Knotless Fixation Implant System is intended for the fixation of soft tissue to bone during rotator cuff repair.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(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

510(k) Number K073226