510(k) SUMMARY

MAR 12 2008

Micro QA+ with #3-0, #4-0 Orthocord Anchor /
Microfix QA+ with #3-0, #4-0 Orthocord Anchor

Submitter's Name and Address:

DePuy Mitek
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Contact Person

Kristine Christo
Senior Regulatory Affairs Specialist
DePuy Mitek
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767
Telephone: 508-828-3359
Facsimile: 508-977-6955
e-mail: KChristo@Dpyus.jnj.com

Name of Medical Device

Classification Name: screw, fixation, bone

Common/Usual Name: Appliance for reconstruction of soft tissue to bone

Proprietary Name: Micro QA+ Anchor / Microfix QA+ Anchor

Substantial Equivalence

Micro QA+ Anchor with Orthocrod is substantially equivalent to: Micro QA+ Anchor, K032078, K982420, K962793 and K962511, manufactured by DePuy Mitek.

Microfix QA+ Anchor with Orthocord is substantially equivalent to: Microfix QA+ Anchor, K024115, manufactured by DePuy Mitek

Device Classification

Bone anchors/screws are classified by the FDA as Class II Medical Devices under the generic category of

* Single/Multiple component metallic bone fixation appliances and accessories
* Smooth or threaded metallic bone fixation fattener

Micro QA+ : Single / multiple component metallic bone fixation appliances and accessories under 21 CFR 888.3040. Product Code: JDR

Microfix QA+: Smooth or threaded metallic bone fixation fattener under 21CRF 888.3040. Product Code: HWC

Device Description

Micro QA + with #3-0 Orthocord or #4-0 Orthcord / Microfix QA+ with #3-0 Orthocord or #4-0 Orthcord are a preloaded, disposable suture anchors/ inserters assembly for soft tissue repair to bone in the hand and skull.

The anchor is dimensionally identical anchor to that of the Micro QA+ Anchor with Ethibond #3-0 Orthocord or 4-0 Orthocord / Microfix QA+ Anchor with Ethibond #3-0 Orthocord or 4-0 Orthocord .

Indications for Use

Microfix QA+: The Microfix QuickAnchor Plus is indicated for fixationof soft tissue to bone, using suture for the indications listed below.

Hand: Hand: Repair / reconstruction of collateral ligaments, flexor and extensor tendon at the PIP (proximal interphalaangeal), DIP (distal interphalaaangeal), and MCP (metacarpal interphalangeal) joints for all digits.

Skull: Soft tissue attached to the parietal. Temporal ridge, frontal, mandible, maxilla, zygoma, and periobital bones of the skull.

Micro QA+: The Micro QuickAnchor Plus(Micro QA+) is indicated for fixation of non-absorbable braided polyester or partially absorbable braided composite surgical suture to bone. This product is intended for the indications listed below:

Hand: Repair / reconstruction of collateral ligaments, flexor and extensor tendon at the PIP (proximal interphalaangeal), DIP (distal interphalaaangeal), and MCP (metacarpal interphalangeal) joints for all digits.

Skull: Lateral canthoplasty

Safety and Performance

The determination of substantial equivalence for this device was based on a detailed device description, and conformance to consensus and voluntary standards. Bench testing was performed demonstrating that the Micro QA+ Anchor with #3-0 and #4-0 Orthocord / Microfix QA+ Anchor with #-0 and #4-0 Orthocord met predetermined acceptance criteria.

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Micro QA+Anchor and Microfix QA+ Anchor has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Mitek
% A Johnson & Johnson Company
Ms. Kristine Christo
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, MA 02767

MAR 12 2008

Re: K080352
Trade/Device Name: Micro QuickAnchor Plus and Microfix QuickAnchor Plus
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, JDR, MAI
Dated: February 8, 2008
Received: February 11, 2008

Dear Ms. Christo:

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

510(k) Number (if known): K080352

Device Name(s): Micro QuickAnchor Plus (Micro QA+ Anchor)

Indications for Use:

The Micro QuickAnchor Plus is indicated for fixation of non-absorbable braided polyester or partially absorbable braided composite surgical suture to bone. This product is intended for the indications listed below:

Hand: Repair / reconstruction of collateral ligaments, flexor and extensor tendon at the PIP (proximal interphalaangeal), DIP (distal interphalaaangeal), and MCP (metacarpal interphalangeal) joints for all digits.

Skull: Lateral canthoplasty

Device Name(s): Microfix QuickAnchor Plus (Microfix QA+ Anchor)

Indications for Use:

The Microfix QuickAnchor Plus is indicated for fixationof soft tissue to bone, using suture for the in dications listed below.

Hand: Hand: Repair / reconstruction of collateral ligaments, flexor and extensor tendon at the PIP (proximal interphalaangeal), DIP (distal interphalaaangeal), and MCP (metacarpal interphalangeal) joints for all digits.

Skull: Soft tissue attached to the parietal. Temporal ridge, frontal, mandible, maxilla, zygoma, and periobital bones of the skull.

Prescription Use ___√___ AND/OR Over-The-Counter Use ___No____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Nathan Oyler for mxm

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K080352