FEB 29 2012

SECTION 2 - 510(k) SUMMARY

HEALIX ADVANCE™ BR Anchor

Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767

Contact Person	Yayoi Fujimaki Regulatory Affairs Senior Associate DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA	Telephone: 508-828-3541 Facsimile: 508-977-6911 e-mail: yfujima1@its.jnj.com

Name of Medical Device	Proprietary Name:	HEALIX ADVANCE™ BR Anchor
	Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
	Common Name:	Bone Anchor

Substantial Equivalence Facility	The HEALIX ADVANCE BR Anchor is substantially equivalent to: ▪ K073412: Healix BR Anchor and Gryphon BR Anchor ▪ K100012: Gryphon T and P BR Anchor

Device Classification	Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MAI regulated under 21 CFR 888.3030.

Device Description	The HEALIX ADVANCE BR Anchor is absorbable threaded suture anchor preloaded on a disposable inserter assembly intended for fixation soft tissue to bone. The suture options may include needles to facilitate suture passage through tissue. HEALIX ADVANCE BR Anchor is provided sterile and is for single patient use only.	
Indications for Use	**Shoulder:**	Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;
	Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;
	Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis;
	Elbow:	Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction;
	Hip:	Capsular repair, Acetabular Labral Repair.
Safety and Performance	**Non-clinical Testing** Design verification activities, such as Anchor Torque, Anchor Pull Out (at T=0 and *in vitro* testing throughout the healing period) were performed against pre-defined acceptance criteria according to the intended use, Results of performance testing have demonstrated that the proposed devices are suitable for their intended use. Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed HEALIX ADVANCE BR Anchor has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Mitek Inc.
% Ms. Yayoi Fujimaki
Regulatory Affairs Senior Associate
325 Paramount Drive
Raynham, Massachusetts 02767

FEB 29 2012

Re: K120078
Trade/Device Name: HEALIX ADVANCE™ BR Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: January 9, 2012
Received: January 10, 2012

Dear Ms. Fujimaki:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: HEALIX ADVANCE™ BR Anchor

Indications for Use:

The **HEALIX ADVANCE™ BR Anchor** is indicated for:

Shoulder:	Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction;
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair;
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis;
Elbow:	Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction;
Hip:	Capsular Repair, Acetabular Labral Repair.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120078