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510(k) SUMMARY

Doubleplay™ Suture Anchor

Applicant Biocomposites Ltd
Keele Science Park
Keele
Staffordshire
England
ST5 5NL

Contact Person Mr Simon Fitzer
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Classification Name: Fastener, fixation, biodegradable, soft tissue
Common/Usual Name: Suture anchor, bone anchor
Trade/Proprietary Name Doubleplay™ Suture Anchor
Product Code HWC

Legally Marketed Predicate Devices

Trade Name	Manufacturer	510(k) No
Arthrex Bio-Corkscrew Suture Anchor	Arthrex Inc	K043337
Model 5000 AxyaLoop Bone Anchor	Axya Medical Inc	K041698

Device Description

The Doubleplay™ Suture Anchor is a bioabsorbable device manufactured from Bilok®, a composite mixture of poly-L-lactic acid (a synthetic bioabsorbable polymer) and calcium phosphate (bone void filler material). It may be supplied with sutures with or without pre-attached needles.

Intended Use / Indications

The Doubleplay™ Suture Anchor is intended for fixation of suture to bone in orthopaedic procedures.

The indications, contraindications, risks and potential adverse events are the same as the identified predicate devices and are thus substantially equivalent.

Summary of Technology

The Doubleplay™ Suture Anchor has the same technological characteristics as the predicate devices and any differences do not raise concerns concerning safety and effectiveness.

Non Clinical Testing

Test data supplied demonstrates that the Doubleplay™ Suture Anchor is substantially equivalent to the predicate devices and any differences do not raise concerns concerning safety and effectiveness.

Clinical Testing

The material used in the manufacture of the Doubleplay™ Suture Anchor has been used in other bone site applications for approximately eight years with no reported incidents of material related adverse events. Implant studies show that the material is not resorbed in less than 12 months. This is greater than the expected bony healing period which is typically 12 weeks. The tissue to bone healing period is typically 6-8weeks.

Substantial Equivalence

Documentation provided demonstrates that the Doubleplay™ Suture Anchor is substantially equivalent to the legally marketed predicate devices in basic features and intended uses. No new concerns have been identified regarding safety and effectiveness of the new device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2006

Biocomposites Ltd
% Mr. Simon Fitzer
Quality & Regulatory Affairs Manager
Keele Science Park, Keele
Staffordshire, England ST5 5NL

Re: K061949
Trade/Device Name: Doubleplay™ Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, JDR
Dated: June 30, 2006
Received: July 10, 2006

Dear Mr. Fitzer:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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

INDICATIONS FOR USE

510(k) Number (if known): K061949

Device Name: Doubleplay™ Suture Anchor

Indications For Use:

The Doubleplay™ Suture Anchor is intended for fixation of suture to bone in orthopaedic procedures in the shoulder, foot/ankle, knee, hand/wrist, elbow and pelvis.

Prescription Use ✓ OR Over-The-Counter use No
(Part 21 CFR 801 Subpart D) (Part 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)

Barbara Mechum for MKM

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

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