

MAY 17 2007

**510(k) SUMMARY**

**Bilok® Screw**

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

**Contact Person** Mr Simon Fitzer  
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Email: [sf@biocomposites.com](mailto:sf@biocomposites.com)

**Classification Name:** Screw, fixation, bone  
**Common/Usual Name:** Bone screw  
**Trade/Proprietary Name** Bilok® Screw  
**Product Code** HWC  
**CFR Section** 21CFR888.3040

**Device Description**

The Bilok® Screw is a cannulated, sterile, single use bone screw manufactured from a composite mix of calcium phosphate and poly L-lactic acid (PLLA).

**Intended Use / Indications**

The Bilok® Screw has the exact same intended use and indications as the predicate device.

The Bilok® Screw is indicated for use in anterior cruciate ligament (ACL) reconstruction procedures where the surgeon places the graft in tibial and/or femoral tunnels and inserts screws between the tunnel wall and graft to hold the graft in place.

The Bilok® Screw is used to provide interference fixation of patellar bone-tendon-bone grafts in ACL reconstruction.

The Bilok® Screw is used to provide interference fixation during femoral and/or tibial fixation in ACL reconstruction using a soft tissue graft (semi-tendonosis gracilis).

### **Summary of Technology**

The Bilok<sup>®</sup> Screw has the same technological characteristics as the legally marketed predicate device and any differences do not raise any concerns regarding safety and effectiveness.

### **Non Clinical Testing**

Documentation provided demonstrates that the Bilok<sup>®</sup> Screw is substantially equivalent to the legally marketed predicate device and any differences do not raise any concerns regarding safety and effectiveness.

### **Substantial Equivalence**

Documentation provided demonstrates that the Bilok<sup>®</sup> Screw is substantially equivalent to the legally marketed predicate device and any differences do not raise any concerns regarding safety and effectiveness.

### **Safety and Performance**

Documentation provided demonstrates that the Bilok<sup>®</sup> Screw is substantially equivalent to the legally marketed predicate device and any differences do not raise any concerns regarding safety and effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K071091

Trade/Device Name: Bilok<sup>®</sup> Screw  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: April 4, 2007  
Received: April 18, 2007

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

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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): K071091

Device Name: Bilok® Screw

Indications For Use:

The Bilok® Screw is indicated for use in anterior cruciate ligament (ACL) reconstruction procedures where the surgeon places the graft in tibial and/or femoral tunnels and inserts screws between the tunnel wall and graft to hold the graft in place.

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Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter use No  
(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)

*Caroline Buchner*  
(Division Sign-Off)

**Division of General, Restorative  
and Neurological Devices**

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