



American Academy of Orthopaedic Surgeons

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DOCUMENTATION OF FDA STATUS FOR USES DESCRIBED

South Carolina Orthopaedic Association Annual Meeting

August 7-10, 2008

The Sanctuary at Kiawah Island Golf Resort, Kiawah Island, SC

To obtain information regarding the clearance status of a device or pharmaceutical refer to the product labeling or call the FDA 1-800-638-2041 or visit the FDA internet site at <http://www.fda.gov/cdrh/510khome.html>

In my 'work' for this educational program or publication:

- The FDA has cleared all pharmaceuticals and/or medical devices for the use described in this presentation.
- The FDA has not cleared the following pharmaceuticals and/or medical devices for the use described in this presentation. The following pharmaceuticals and/or medical devices are being discussed for an off-label use. (see note below)
- Not Applicable

| Manufacturer Name | Drug or Device |
|-------------------|----------------|
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| | |
| | |

⇒ Signature: _____ Date: _____

Print Name: _____

**Please return this form as soon as possible to:
Attention: Fraser Cobbe, Executive Director**

Fax: 813-949-8994

Academy policy provides that "off label" uses of a device or pharmaceutical may be described in the Academy's CME activities so long as the "off-label" status of the device or pharmaceutical is also specifically disclosed (i.e. that the FDA has not approved labeling the device for the described purpose). Any device or pharmaceutical is being used "off label" if the described use is not set forth on the product's approved label.