



American Academy of Orthopaedic Surgeons
6300 N. River Road, Rosemont, IL 60018

DOCUMENTATION OF FDA STATUS FOR USES DESCRIBED

South Carolina Orthopaedic Association Annual Meeting
August 2-5, 2012
The Sanctuary at Kiawah Island

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

⇒ **Signature:** _____ **Date:** _____

Print Name: _____

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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.