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UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES -- GENERAL

Case No. **CV 06-7430-VBF(PLAx)**

Dated: **September 17, 2008**

Title: **Camille Carson -v- Depuy Spine, Inc., et al.**

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**PRESENT: HONORABLE VALERIE BAKER FAIRBANK, U.S. DISTRICT JUDGE**

Rita Sanchez  
Courtroom Deputy

None Present  
Court Reporter

**ATTORNEYS PRESENT FOR PLAINTIFFS:**

**ATTORNEYS PRESENT FOR DEFENDANTS:**

None Present

None Present

**PROCEEDINGS (IN CHAMBERS): COURT ORDER RULING ON SUBMITTED MATTER  
- RENEWED MOTION OF DEFENDANT DEPUY  
SPINE, INC. FOR SUMMARY JUDGMENT**

**I. Ruling**

After considering the papers filed and counsel's oral arguments at the hearing on September 15, 2008, the Court **GRANTS** the Renewed Motion of Defendant Depuy Spine, Inc. for Summary Judgment pursuant to grounds set forth in the moving party's papers as indicated herein. The Court finds as follows:

1. There is no genuine issue that the spinal disk at issue was manufactured in accordance with the specifications which were a part of the Premarket Approval (PMA) issued by the FDA.
  - The evidence is that damage to the device was caused either while implanted in Plaintiff due to movement of her vertebrae, or by the removal surgery itself. Plaintiff does not rebut this or offer other evidence.

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2. There is no genuine issue that Depuy did not violate any FDA regulations governing promotion of a medical device for an off-label use.
  - There is a lack of evidence that Plaintiff's surgeon relied on any promotion of off-label use by Defendant. There is no evidence that the off-label use of the device caused Plaintiff's injuries.

## II. Background

Dr. Michael Kropf implanted two Charite artificial spinal discs in Plaintiff Carson in February 2005. Ms. Carson began to experience severe back pain, and Dr. Kropf removed one of the discs in November of that year. (The removed device was presumably discarded.) In February 2007, Ms. Carson filed a complaint against Defendant disc manufacturer for products liability based on negligence, breach of warranty, and strict liability.

By Order dated June 21, 2007, this Court granted Defendant partial summary judgment on the warranty and strict liability claims, on grounds that the Medical Device Amendments of 1976 preempted those claims. See 21 U.S.C. 360k(a). Those state claims potentially conflicted or added to requirements which the FDA imposed on the device through the premarket approval process. The Court denied Plaintiff's negligence claim except "insofar as she alleges that the Defendants failed to comply with federal device-specific regulations, such as through a manufacturing defect claim." June 21, 2007 Order, p. 10.

## III. Request to Revisit the June 21 Order

As a preliminary matter, Plaintiff, in her Opposition, requests the Court revisit its June 21 ruling on the grounds that the United States Supreme Court's February 28, 2008 decision in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008) "would allow a claim of strict liability based on a manufacturing defect." Opp. at 3. First, Plaintiff should have timely raised this request in a motion for reconsideration, not in a summary judgment opposition more than six months after *Riegel* was decided. Second, the basis for Plaintiff's request is unclear and inadequately briefed.

## IV. Manufacturing-Defect Claim

Plaintiff basically sets forth two grounds from which a jury could infer a manufacturing defect: (1) The accelerated wear of the device observed by Dr. Kropf during the removal surgery, and (2) The breakage of the device into pieces.

