

**Eleventh Circuit Court of Appeals Affirms
Summary Judgment Based On *Riegel v. Medtronic, Inc.***

On March 8, 2011, the United States Court of Appeals for the Eleventh Circuit affirmed summary judgment in favor of Defendant Arrow International, Inc. (“Arrow”), the manufacturer of an intrathecal infusion pump, and other defendants, on federal preemption grounds pursuant to the Medical Device Amendments to the Food, Drug and Cosmetic Act.

Plaintiffs’ cause of action stemmed from an allegedly defective “implantable drug delivery system” consisting of an Arrow Model 3000 30 mL Constant Flow Implantable Pump with Bolus Safety Valve (“infusion pump”) and an Arrow Flextip® Plus Intraspinal Kit, a “system” approved by the Food and Drug Administration through the Premarket Approval process. Plaintiff Wolicki-Gables claimed that, after the original implantation, the infusion pump and/or catheter connector malfunctioned, necessitating a second (revision) surgery. After the second surgery, Plaintiff allegedly developed an infection which resulted in permanent partial paralysis.

Arrow filed a Motion for Summary Judgment, in which the other defendants joined, wherein Arrow argued that Plaintiffs’ claims were preempted by the provisions of the Medical Device Amendments to the Food, Drug and Cosmetic Act as analyzed by the United States Supreme Court in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), and that Plaintiffs could not provide evidence sufficient to sustain their strict liability claim as required under Florida law. The Court specifically concluded that Plaintiffs’ claims were expressly preempted and granted Arrow’s Motion for Summary Judgment. *See Wolicki-Gables v. Arrow Int’l, Inc.*, 641 F. Supp. 2d 1270 (M.D. Fla. 2009).

On appeal, Plaintiffs argued, first, that their claims were parallel and, thus, were not preempted and, second, that they were entitled to a presumption that the catheter connector was defective. The Court rejected both arguments. First, the Court concluded that Plaintiffs “failed to allege facts in their complaint demonstrating the presence of the elements of a parallel claim.” The Court also found that Plaintiffs “failed to demonstrate that a defect in the Arrow pump ‘most probably’ caused her injuries and not some other malfunction or obstruction.”

See Wolicki-Gables v. Arrow Int’l, Inc., 641 F. Supp. 2d 1270 (M.D. Fla. 2009); *Wolicki-Gables v. Arrow Int’l, Inc.*, Case No. 09-14342-EE (11th Cir. 2011).