

## FDA's Approval of Medical Device Bars Products Suit

3rd Circuit joins two others on majority side of split

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A woman who claims a defective heart pump caused her husband's death has lost her bid to revive a products liability suit against the pump's manufacturer now that a divided panel of the 3rd U.S. Circuit Court of Appeals has ruled that all of her state law claims are expressly pre-empted by the federal Medical Device Amendments.

In *Horn v. Thoratec Corp.*, the two-judge majority concluded that since the HeartMate heart pump was subjected to "extensive" scrutiny by the U.S. Food & Drug Administration in a "pre-market approval" process, or PMA, any lawsuit over the pump's design or labeling could result in a judgment that conflicts with those federal requirements.

Thoratec's lawyer, Alan E. Untereiner of Robbins Russell Englert Orseck & Untereiner, also in Washington, argued that McClure was correct in analyzing only the federal side of the equation because the U.S. Supreme Court's 1996 decision in *Medtronic Inc. v. Lohr* made that the only relevant inquiry.

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