

# UTAH MEDICAL PRODUCTS, INC.



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## PRESS RELEASE

### Utah Medical Products' Compliance with QSR Confirmed

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Salt Lake City, Utah - Utah Medical Products, Inc. (Nasdaq:UTMD) announces that the U.S. Federal District Court in Salt Lake City, on October 21, 2005, confirmed that UTMD is operating in compliance with 21 CFR § 820, the U.S. Food & Drug Administration (FDA) Quality System Regulation (QSR).

The Court disagreed with all allegations by the FDA, and dismissed the lawsuit filed in August 2004 that sought to shut down UTMD, without any evidence of unsafe, ineffective, or defective products or products causing any patient harm, until UTMD complied with the FDA's interpretation of the QSR, an interpretation that was never provided to UTMD until after the lawsuit was filed.

According to Judge Bruce S. Jenkins, in the "Memorandum Opinion & Order" dated October 21, 2005,

*"This is an unusual case. The safety of the products manufactured by Utah Medical has never been at issue. Even though product safety is a non-issue, the relief originally sought by the United States was to stop Utah Medical's products from entering commerce because of alleged persistent deficiencies of Utah Medical in complying with the applicable quality system regulations (21 CFR § 820), and asserting that a failure to comply by definition produced an adulterated product and subjected the product and the persons responsible for the product to regulatory action. In short, the United States asked that Utah Medical be ordered to stop the sale of product until Utah Medical complies with the regulation 21 CFR § 820 and in a manner that has been found acceptable to FDA.*

During the extended process carried on by the parties and by the Court in passing on motions and during the pretrial conference, and during the trial itself, the United States on the record softened the relief that it sought to simple regulatory compliance, and abandoned the more draconian relief of stopping sales of product defined as adulterated.

The relief early sought by the United States assumed that compliance with the regulations and in a manner satisfactory to the FDA are the same. But Utah Medical has asserted full compliance with the regulations and insists that the FDA misreads its own regulations."

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“The court has been impressed as well by Utah Medical’s design of product, its record-keeping of each step along the way, the acceptance in the market of its products, the Company’s uniform processing of complaints, and the manner in which change is made in practice and procedure as a result of complaint handling.”

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**“It makes no sense for the court to order Utah Medical to do something they are already doing.”** (emphasis added)

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The full text of the Court’s decision can be accessed on the Internet at [http://www.utahmed.com/pdf/FDA Trial Decision.pdf](http://www.utahmed.com/pdf/FDA_Trial_Decision.pdf).

UTMD will follow-up this announcement with additional comments.

Utah Medical Products, Inc., with particular interest in health care for women and their babies, develops, manufactures, assembles and markets a broad range of well-established disposable and reusable specialty medical devices designed for better health outcomes for patients and their care-providers. For more information about Utah Medical Products, Inc., visit UTMD’s website at [www.utahmed.com](http://www.utahmed.com).