

# UTAH MEDICAL PRODUCTS, INC.



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## PRESS RELEASE

### Utah Medical Products, Inc. Announces Conclusion of FDA Inspection

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Salt Lake City, Utah - Utah Medical Products, Inc. (Nasdaq: UTMD) announces that two FDA investigators have concluded a full QSIT inspection used to assess a medical device manufacturer's compliance with the Quality System Regulation (QSR) and related regulations. The inspectional process, known as the "Quality System Inspection Technique" or QSIT, guides field investigators in conducting an efficient and effective comprehensive inspection, focusing on key elements of a firm's quality system.

FDA investigators use a Form FDA 483 to notify management in writing of significant objectionable observations which, in the investigator's judgment, indicate a medical device is adulterated or prepared under conditions where the device may become adulterated. At the conclusion of the UTMD inspection last Friday, the FDA investigators determined that there was no need to issue a Form FDA 483. In the industry, this is known as a "clean" inspection and evidence that FDA investigators have concluded that the Company is in compliance with FDA requirements for manufacturing medical devices. UTMD appreciates the professionalism and objectivity of the recent investigators.

UTMD believes that this is significant since this inspection was the first FDA inspection of the Company since 2004. After the 2004 inspection, the FDA filed a lawsuit against UTMD alleging that the Company had significant objectionable conditions. The lawsuit was adjudicated in Federal Court in 2005 with the Court concluding completely in UTMD's favor and finding that UTMD's quality system was in compliance with the QSR.

According to CEO Kevin Cornwell,

"For anyone – customers, potential customers, clinicians, hospital administrators and others in the medical device supply chain - who had doubts or concerns that the FDA had issues with UTMD's quality system, the results of this recent inspection should lay those to rest. The millions of UTMD devices used in critical care situations with expected outcomes are clear evidence that UTMD's quality system overall is working as intended in the QSR, and consistent with UTMD's decades of commitment to excellence."

Utah Medical Products, Inc., with particular interest in health care for women and their babies, develops, manufactures, assembles and markets a broad range of disposable and reusable specialty medical devices.