## **UTAH MEDICAL PRODUCTS, INC.**



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## **PRESS RELEASE**

## **UTMD Updates Status of FDA Inspection**

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Salt Lake City, Utah - On February 11, Utah Medical Products, Inc. (NASDAQ: UTMD) publicly disclosed a comprehensive inspection of its Utah facility by three FDA inspectors from Minneapolis, Dallas and Denver which began on February 2. On March 4, UTMD reported conclusion of the inspection after five weeks and issuance of FORM FDA-483 with inspectors' observations.

In response to shareholder questions regarding the results of the inspection, UTMD announces that on March 16, it responded in detail to each of the seven FDA-483 observations. The fifty-eight (58) page response letter appended five exhibits of over six hundred (600) additional pages.

After a 2002 inspection, UTMD received a FDA-483 with thirteen (13) observations. After a 2003 inspection by two inspectors, one of whom was a questionable FDA "expert" in sterilization, UTMD received a FDA-483 with nineteen (19) observations, including primary observations that included statements that UTMD did not have any evidence of sterilization validation or follow procedures for making proper MDR (injury) reports. If these observations had been true, FDA could have had a basis to make accusations against UTMD. UTMD has been firm in expressing its disagreement with the FDA and is particularly pleased that neither of those issues was included in the 2004 FDA-483, because the same quality system documentation that was reviewed in 2003 was reviewed in 2004.

UTMD believes its longstanding position has been vindicated on the basis that the adequacy of UTMD's QSR procedures that have been in existence for years has been verified. There were no current observations to suggest or support concern about the safety or effectiveness of any devices manufactured and distributed by UTMD. This last fact represents to UTMD the continuing confirmation of the effectiveness of the UTMD Quality System that has been in place since prior to the 2001 inspection and contradicts the position expressed by the FDA Denver District Office in 2001.

The primary observation in the most recent 2004 FDA-483 alleges UTMD lacks validation of its injection molding and extrusion operations. Yet, UTMD has received supportive opinions from independent experts, one of whose active involvement in the plastics industry includes training of FDA inspectors. Other observations represented inspectors' opinions (not failure to follow explicit FDA requirements), or were simply incorrect in part because of failure to place the observation into proper context. When a handful of isolated and minor documentation errors, which did not affect the quality of devices manufactured, were identified these were promptly corrected. The rare documentation errors were identified through review of thousands of pages, and represented isolated human errors that did not affect the integrity of the UTMD Quality System.

As part of the March 16 written response, UTMD offered additional clarification and further dialogue if needed to provide a fully exhaustive discussion of any issues resulting from the inspection. UTMD and its consultants believe that the FDA has sufficient evidence to support that UTMD has been and is in compliance with a reasonable interpretation of the QSR and regards the FDA delay in

acknowledging this fact as further evidence of continued improper performance by numerous FDA personnel. Given the scope of the improper behavior, UTMD believes that its experience is not isolated within the industry. We again urge our Congressional representatives who have a keen interest in the public health, a desire to support innovation for an industry where regulators are often responsible for its decline, and a sincere concern about jobs for law-abiding citizens, to examine UTMD's experience as part of a formal investigation of current FDA practices.

UTMD advises that its devices are of state of the art quality preferred in particular by sophisticated clinician users, and that its devices conform to the quality and performance represented by UTMD.

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 designed for better health outcomes for patients and their care-providers. For more information about Utah Medical Products, Inc., visit UTMD's website at <u>www.utahmed.com</u>.