

# UTAH MEDICAL PRODUCTS, INC.



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## PRESS RELEASE

### UTMD Reports Conclusion of FDA Inspection

March 4, 2004

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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.

In response to shareholder questions regarding the status of the inspection, UTMD announces that on March 3, the inspection ended with the presentation of seven observations in a Form FDA-483, which the Company reviewed completely with the inspectors. These observations relate to only 6 of more than 150 subsections of the FDA Quality System Regulation (QSR). UTMD is now preparing a written response to the FDA regarding the observations. The inspection, which consumed 56 inspector-days, reviewed many thousands of pages of quality system documents including device history records, procedures, complaints and complaint investigations, nonconformance reports, deviation/ waivers, corrective action reports, process control records including statistical process control parameters, meeting minutes, bills of operation, set-up sheets, calibration reports, process validation records, sterilization records, test reports including raw data and many other documents. Considering the extent of the inspection, UTMD believes the observations are relatively few, easily explained and some not supportable.

At the conclusion of the 2003 inspection by two inspectors for almost three weeks, UTMD received a FDA-483 with 19 observations which relate to specific subsections of the QSR. These observations were explicitly reviewed again in the present inspection. Some of the key previous observations, for example, alleged lack of proper sterilization validation where the Company's same documentation was available to inspectors in 2002 and 2003 inspections, did not reappear on the current FDA-483.

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 statement represents to UTMD the continuing confirmation of the effectiveness of the UTMD Quality System that has been in effect since prior to the 2001 inspection which resulted in an FDA Warning Letter, and consistent with the unqualified ISO certifications UTMD has enjoyed since 1994, long before the FDA modified its GMP regulation to conform with the criteria and objectives of the ISO. The ISO standards are quality system standards used by most countries around the world including the U.S.

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.

Investors are cautioned that this press release contains a forward looking statement, and that actual results may differ from those projected. Risk factors that could cause results to differ materially from those projected include FDA reviewers' perspective of the observations noted on the 2004 FDA-483

and their willingness to enter into a dialogue with the Company to resolve any disagreements, which to date has not occurred since the 2002 inspection.

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 [www.utahmed.com](http://www.utahmed.com).