

# UTAH MEDICAL PRODUCTS, INC.



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## PRESS RELEASE

### **UTMD Discloses Recent U.S. Sales Activity and Share Repurchases**

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Salt Lake City, Utah - On August 10, 2004, the U.S. Food & Drug Administration (FDA) announced that it would seek an injunction against Utah Medical Products, Inc. (Nasdaq: UTMD) until it has corrected alleged "deviations" from the Quality System Regulation (QSR). UTMD has responded with its own press releases of August 10, 11 and 16.

There remain no restrictions on UTMD's ability to manufacture and distribute its proven safe and effective devices.

However, the FDA Press Release has caused significant disruption to UTMD's business, in part because of inappropriate activities of UTMD competitors incorrectly telling customers that the company has been, or is about to be, shut down.

In subsequent correspondence with the Secretary of HHS and the FDA, UTMD has objected to the FDA Press Release and comments to the news media since there are no violations until properly proven in a Court of law. There neither has been, nor is there now, any FDA issue about the safety or effectiveness of UTMD's devices manufactured through the efforts of nearly 200 employees utilizing manufacturing processes which haven't significantly changed in over 10 years. There is objective evidence that millions of UTMD's products used each year have consistently met and continue to meet predetermined specifications. Throughout that same span of time, UTMD has maintained a quality system certified per ISO 9001, and more recently ISO 13485. Yet statements made in the Press Release and media quotes by an FDA representative wrongly characterized UTMD's practices and devices. These unproven statements have been and are harmful to UTMD's business and reputation.

UTMD has asked that the FDA stop making statements for which the proof is to be established through a judicial process which we respect. We hope the government shares in this respect. The proper and fair forum to determine whether FDA allegations are supportable is through the judicial process and not through the powerful and damaging access to the press that has been used by the FDA. The safety and effectiveness of UTMD devices historically and since the 2001 inspection is confirmed by the fact that the FDA has not applied any of its vast array of administrative authorities to question clinical use.

Thankfully, many customers are well aware of the safety and effectiveness of UTMD's devices and this continuous long term proven result could not have been accomplished if UTMD's quality systems were inadequate.

The nature of UTMD's U.S. hospital business is fast response, where about 90% of orders are shipped within two days of receipt. Hence, UTMD operates on a low backlog and any interruptions to its business are immediately felt. Although it is not clear what longer term changes may take place, UTMD is pleased to report to shareholders that in the three weeks since the FDA Press

Release the total dollar value of orders has remained about normal. Going forward, the ten percent discount announced on August 20 as a U.S. direct customer Reward Program may have a significant effect on net sales, unless UTMD gains additional business as a result of it.

UTMD reminds customers that orders can be placed conveniently by calling Customer Service at (800) 533-4984, sending a fax to (801) 566-2062, or accessing on-line at [www.order.utahmed.com](http://www.order.utahmed.com).

On August 30, UTMD filed a formal Answer to the FDA Complaint in which it has denied all of FDA's allegations of regulatory violations. The Answer is available for public review by contacting the U.S. District Court. The FDA has raised no evidence to contradict that UTMD devices are safe and effective for their intended purpose, and no evidence to support that failure to comply with any regulation "decreases the level of assurance that its products are safe and effective." This latter allegation by the FDA to the media but not in the lawsuit is false and misleading absent clear evidence of support. Although UTMD respects the role of the FDA, it remains committed to seeking the fair and honest treatment from the government that it has been denied for the last three years.

UTMD's normal practice is to avoid announcing interim results or activities, but the current situation after the August 10 FDA Press Release is unusual. In August through the first week following the FDA Press Release, UTMD repurchased 176,200 of its shares, about 4% of shares outstanding, in the open market at an average cost including commissions of \$17.48 per share. Although no shares have been repurchased by the Company since August 17, UTMD's board of directors remains committed to enhancing shareholder value by repurchasing shares when the shares appear to be undervalued.

Unless UTMD determines that it needs further interim reports to ensure proper fair disclosure to investors, the Company does not anticipate additional announcements of its performance prior to the next regular release of financial results for 3Q 2004, which should take place on or about October 19.

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, proven safe and effective, disposable and reusable specialty medical devices.