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## PRESS RELEASE

### UTMD Responds to On-going Customer Questions Prompted by Competitors

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"The reports of my death are greatly exaggerated." ...Mark Twain

Salt Lake City, Utah – In August, Utah Medical Products, Inc. (Nasdaq:UTMD) published a number of its own press releases in response to an August 10, 2004 press release from the U.S. Food & Drug Administration (FDA) which has unfairly caused some concern regarding the continued use of UTMD's products. UTMD would like to remind shareholders, customers and others that they can conveniently find these press releases stating UTMD's position by accessing [www.utahmed.com](http://www.utahmed.com) on the Internet.

Unfortunately, UTMD's competitors, instead of appreciating that UTMD is also challenging systemic deficiencies within the government that affect responsible manufacturers in the device industry, have tried to take advantage of the situation through innuendo to customers that UTMD may be imminently shut down. This is false, as explained in more detail below.

In order to defend the interest of its stakeholders, not the least of whom are patients that should not be denied UTMD's unique life-saving products, UTMD wishes to refresh its position:

- **Two months after the FDA press release, UTMD continues to manufacture and distribute all of its products worldwide without any regulatory restriction.**
- **There has been no mandated recall or any other regulatory enforcement action that restricts customers from using UTMD's products.**
- **There has not been, and is not now, any allegation by the FDA that UTMD's products are not safe or effective.**
- **There is no FDA claim of defective products or products not conforming to specifications.**
- **The proven extremely low product liability risk using UTMD's products has not changed.**

The FDA, after completing four comprehensive inspections of UTMD's internal quality system in three years, requested an injunction that would halt production and distribution while the company fixes alleged "violations" which have not yet been proven. UTMD, supported by a variety of independent respected experts after evaluating its manufacturing practices, vehemently denies that there are violations of the Quality System Regulation (QSR). UTMD seeks to confirm decades of successful device manufacturing against a paper-driven FDA.

The FDA-483 forms submitted by inspectors after each inspection contain "observations" which are not, according to the FDA's own policies, considered "violations" by the agency until reviewed by superiors and linked to provisions of the QSR. (See The Wall Street Journal, 9/29/04, "FDA Is

Questioned on Report About Red Cross Unit in Atlanta.”) Since this dispute began in 2001, no reviewer or superior from the FDA has ever identified or discussed with UTMD what is inadequate about any of UTMD’s detailed written responses to FDA-483 observations, or any QSR linkages. The FDA-483 observations regarding UTMD’s documentation, remarkably, changed substantially from inspection to inspection without any significant changes made by UTMD. In the latest 2004 inspection by three inspectors over a five week time span, the number of FDA-483 observations declined dramatically from the previous 2003 inspection, and those relating to sterilization disappeared without any change to UTMD procedures.

A U.S. Federal Court in Salt Lake City will decide if the FDA’s request for injunction has any merit. The Court has set a schedule for discovery which will lead to a trial, if it happens at all, no earlier than June 2005. Any reference to an imminent shut down of UTMD is obviously false.

The paradox for UTMD’s customers that is being unscrupulously exploited by competitors is “How could this (the FDA’s press release that UTMD is violating the QSR) not be true?” UTMD asks other parties to consider whether the FDA is always right in what it does. Interestingly, the FDA has not sought a preliminary injunction against UTMD, which would be in the public interest if there were a device quality issue. This appears to be virtually unprecedented in a case where they seek such severe action against a company. It is also interesting that the FDA appears to be in no hurry to have their claims adjudicated, given they first requested a trial date in August 2005. Before we arrive at the point in time for a trial, UTMD believes there will be other public information that will reassure customers that an interruption in distribution of UTMD’s products will not happen.

Investors are cautioned that this press release contains forward looking statements and that actual events may differ from those projected.

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).