

# UTAH MEDICAL PRODUCTS, INC.



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## PRESS RELEASE

### Utah Medical Products, Inc. Sends Letter to Its Customers

August 11, 2004

Salt Lake City, Utah - The following letter is being sent to Utah Medical Products, Inc. (Nasdaq: UTMD) customers from Chairman and CEO Kevin Cornwell:

I want to express some frank words about Utah Medical Products, Inc.'s (UTMD's) current experience with the Food and Drug Administration ("FDA"), and some explanation regarding a dispute that is now public.

All medical device manufacturers are subject to regulation by the Food and Drug Administration. This includes inspection of manufacturing facilities by FDA employees, most of whom have never had a responsibility to manufacture a device or experience in the manufacturing of a device. Everyone; manufacturers, clinical users and patients; benefit from an agency that is competent and strong.

Since 2001, UTMD has been subject to repeated and extensive inspection by these FDA employees. While their observations often represent unqualified opinions which are not backed by law or regulation, at no time has there ever been any evidence to support a concern about either the safety or effectiveness of our devices. Although we have consistently responded comprehensively in writing to inspectors' observations, FDA supervisory and management personnel have refused for nearly three (3) years to engage in dialogue with UTMD that would identify a violation of the Quality System Regulation (QSR), also known as GMPs (Good Manufacturing Practices). A variety of independent experts have been retained by UTMD to evaluate our manufacturing practices. They have concluded that UTMD does comply with a reasonable interpretation of applicable laws and regulations, including the QSR. UTMD is comforted by this fact, and welcomes the opportunity presented by the recent complaint filed by the FDA to confirm through a trial process what our reputation over twenty-five (25) years has established; namely, that clinician users can rely on the quality and performance of UTMD's devices. Despite the FDA publicized complaint, there is no restriction placed on UTMD to limit manufacture or distribution of any of its devices.

Ironically, a key distinction of UTMD's products proven clinically over the years is that our quality products help reduce risk. The confidence that you have displayed in our devices is sincerely appreciated. I assure you that UTMD neither has nor will it diminish its commitment to manufacture devices of the greatest quality. Please reflect on your personal experience using our products, and continue to give us your support.

In summary,

- There are no restrictions limiting your use of UTMD's products. There are no restrictions limiting our manufacture or distribution of products.
- FDA claims have to be formally adjudicated. UTMD is innocent until proven otherwise. We regret it if the FDA's public statements give an unfair implication of guilt.

- There has never been, nor is there now, an FDA allegation that UTMD's products are not safe and effective.

Sincerely,

Kevin L. Cornwell

Chairman and CEO