

# UTAH MEDICAL PRODUCTS, INC.



CORPORATE HEADQUARTERS  
7043 South 300 West  
Midvale, Utah 84047  
Telephone: 801-566-1200  
FAX: 801-566-2062  
NASDAQ Symbol: UTMD  
www.utahmed.com

---

## PRESS RELEASE

### UTMD Further Comments on FDA Complaint and FDA Employee Comments

August 10, 2004

Contact: Kevin L. Cornwell  
(801) 566-1200

Salt Lake City, Utah - Utah Medical Products, Inc. (Nasdaq: UTMD) is responding to a Press Release issued today and comments made by Food and Drug Administration (FDA) employees which UTMD believes are deliberately misleading to the reader.

The complaint which the FDA filed and publicized has not been served on UTMD. However, UTMD understands that the content of this complaint is standard and that the FDA has the burden to prove its allegations. An answer to the complaint will be filed, but UTMD believes in the judicial process and welcomes the opportunity to seek the discovery it has been denied for over three years.

Neither the complaint nor any direct FDA communications to UTMD has identified or suggested any issue relating to the safety or effectiveness of UTMD devices. This fact coupled with ISO 13485 Certification are continuing verification of the superiority of UTMD quality systems. Users of UTMD devices can take comfort in the quality and performance of its devices.

UTMD Chairman and CEO Kevin Cornwell, after reviewing statements made by FDA employees, had this to say:

"It is unfortunate that FDA would publicize comments that border on hearsay and attribute them to Acting Commissioner Lester M. Crawford and Larry Spears. I spoke personally on two very recent occasions with Les Crawford and he never expressed any concern about the performance of any of our devices. The statements attributed to him are not supported by fact and I confirm that users can continue to expect that our devices are safe and effective. The employees that provided the information underlying the statements do not and, to our knowledge, never have had the responsibility to manufacture any medical device.

While disappointed in the comments attributed to Crawford, I am very troubled by the hearsay comments attributed to Larry Spears. The FDA makes allegations of violations/deviations in the hundreds of Warning Letters it issues annually. Yet, it is rarely challenged to prove these allegations. There is not and never has been an imminent public health risk relating to UTMD's products, and this statement attributed to Mr. Spears is correct: "There's not a serious enough problem to say ..." that. As a matter of fact, the FDA has a variety of remedies to address device risks without any resort to the courts. None of these has ever been applied to any UTMD device, because none has been justified.

Finally, an attorney from FDA indicated as long ago as last October that this case does not involve any allegations of defective products. This case instead involves QSR allegations that the agency has been unable to substantiate.”

UTMD maintains support for the quality, performance, safety and effectiveness of devices in distribution as these are manufactured daily by dedicated employees complying with procedures that have been verified by independent experts. The prospect of litigation is rarely welcome, but UTMD is confident that when the FDA’s allegations are scrutinized by the Court, aided by the power of discovery, that UTMD will prevail.