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PRESS RELEASE

UTMD Updates Status of FDA Lawsuit

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Salt Lake City, Utah - Utah Medical Products, Inc. (Nasdaq: UTMD) continues its efforts to discover the basis for a lawsuit filed eight months ago by the Food and Drug Administration (FDA or Agency) in the U.S. District Court in Salt Lake City, alleging failure to comply with the FDA Quality System Regulation (QSR). The discovery of documents and deposition testimony of responsible FDA personnel provides considerable doubt about FDA management of its resources and procedures, and interpretation of the QSR.

UTMD, consistent with the stated intent of the QSR "to ensure that finished devices will be safe and effective…" implemented and maintains procedures since the QSR became effective in 1997. On November 16, 2004, UTMD announced that a FDA designated enforcement official admitted under oath that the FDA is not claiming that UTMD's devices are unsafe, ineffective, defective, or causing any patient harm. UTMD welcomed these admissions and assures users that it continues to manufacture safe and effective devices without interruption.

CEO Kevin Cornwell states,

> "We remain disappointed and surprised by the conduct of personnel within the FDA who are responsible for this aggressive and unnecessary lawsuit against UTMD and its employees. Our desire has always been to manufacture and distribute devices of the highest quality. I believe our procedures meet those directed by the QSR, conform to ISO 13485 certification, and result in release of high quality devices that perform as intended. As the discovery process continues, I am confident that there is credible evidence to support responsible criticism of FDA performance."

During the last four months, scores of FDA documents that would not otherwise have seen the light of day have been produced through the fairness required by the litigation process. Additionally, testimony under oath has been provided by numerous FDA personnel including FDA device specialists and national experts. One of the national device experts was Monica Wilkins, a FDA official who formerly reviewed inspection reports, and made recommendations for regulatory actions including injunctions. As part of her testimony under oath about her five weeks' duration inspection of UTMD during 2004 along with two FDA device specialists, Ms. Wilkins made a number of statements that support UTMD's position.

The questions (denoted "***Q***") are being asked by UTMD legal counsel. The answers (denoted "***A***") are provided by Ms. Wilkins under oath.

> ***Q.*** So you found no evidence during the 2004 inspection that there were procedures required by the regulations that did not exist; is that true?
> ***A.*** What I recall, I don't remember citing anything specific to that, so that would be correct.

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> ***Q.*** All I can ask you about is what you've reviewed, and based on what you reviewed during the 2004 inspection, you found no evidence of Utah Medical failing to follow its own procedures; is that true?
> ***A.*** That is true.

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> ***Q.*** And through looking at all of those records, you didn't come up with a single example in which you believed a corrective action should have been open[ed] but wasn't; is that correct?
> ***A.*** ….no, I did not find any instance where they did not take corrective action.

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> ***Q.*** That's the words I'm using. There was no observation from the 2004 inspection that a corrective action should have been open[ed] but wasn't; is that true?
> ***A.*** Yes, correct.

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> ***Q.*** For the corrective actions that had been fully pursued and completed, you did not see any example of a corrective action that was undertaken but undertaken improperly; is that correct?
> ***A.*** Correct, for the sample of records I reviewed.

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> ***Q.*** We've gone through a number of observations today in which you reached a different conclusion than the prior investigator.
> ***A.*** That is correct.

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> ***Q.*** Do you ever remember another inspection in which there were so many observations that you reached a different conclusion than the prior inspector?
> ***A.*** That I wouldn't recall without looking at specific information.

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CEO Kevin Cornwell states,

> "The Federal Court will interpret the evidence presented by the government and UTMD to decide whether or not UTMD is in compliance with the QSR.

> We sincerely regret that the FDA selected this avenue to discuss our disagreement with observations and opinions made by FDA investigators and reviewers who never have had the training, responsibility or experience to manufacture medical devices. Our efforts to exercise our option to “disagree with any agency decision, action, or operation without fear of retaliation” as expressed in a required attachment to the FDA 482 announcement of inspection was rejected and ignored. Our repeated requests for feedback regarding UTMD’s detailed written responses to FDA-483 observations were ignored. Our multiple appeals to supervisory personnel were ignored. Our request to mediate prior to filing of the lawsuit was ignored. This was not the reception we expected when we sought to exercise our option to disagree in the year 2001.
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> The facts do not support the FDA’s characterization of UTMD in its lawsuit. UTMD has dedicated, well-trained personnel who understand the importance of accuracy and following procedures in the course of manufacturing millions of specially hand-assembled devices. As UTMD proceeds to discover the truth, the whole truth, and nothing but the truth, we hope that the new representatives of this Administration will recognize that this lawsuit was neither justified nor necessary. Moreover, we truly believe that the right thing for the government to do is to acknowledge the great performance of UTMD during a long history of providing safe and effective medical devices for the benefit of health care providers and their patients.”

For the benefit of shareholders, UTMD affirms its belief in previous statements in press releases about its conscientious compliance with the QSR, as well as significant deficiencies in the FDA’s performance, which have been increasingly supported by the evidence in discovery to date. For the benefit of customers, UTMD continues to manufacture and distribute all of its safe and effective products worldwide without any regulatory restriction.

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.