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PRESS RELEASE

UTMD Responds to Notice of FDA Complaint

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Salt Lake City, Utah - Utah Medical Products, Inc. (Nasdaq: UTMD) has just learned through a press release issued by the Food and Drug Administration (FDA) that it seeks to enjoin UTMD from alleged deviations of the Quality System Regulation (QSR).

The filing of this lawsuit does not affect the continued manufacture and distribution of UTMD's devices. UTMD CEO Kevin Cornwell states, "We are innocent until the government proves otherwise. There's never been an FDA allegation that UTMD is not producing safe and effective products." In its twenty-five (25) year history of inventing, manufacturing and marketing medical devices for critical care applications, UTMD has never been prevented from distributing its devices for domestic or foreign use.

This lawsuit follows a February-March five (5) week long comprehensive inspection by three FDA inspectors intended to ascertain UTMD's current compliance with the QSR, which ended with the issuance of a seven (7) item FDA-483, and a March 16, 2004 six hundred (600) page written response by UTMD. In addition to not receiving any FDA feedback to its detailed written explanations, repeated requests by UTMD to discuss any unresolved issues with FDA have been denied. In May, UTMD's request for mediation was rejected by Tim Ulatowski, Director, Office of Compliance in the Center for Devices and Radiological Health (CDRH), FDA.

Six months after the beginning of the last inspection, the filing of this lawsuit follows UTMD's July 20 press release announcing 2Q 2004 results and its belief "that this (FDA) abuse of process should not be tolerated because it damages the public health by reducing continued prospects for innovation by, and survival of, smaller companies which simply expect that FDA employees discharge their obligation to communicate promptly with fairness and honesty."

The present dispute developed as a result of a September 2001 Warning Letter that was issued to UTMD after an inspection by the FDA of its facilities in Midvale, Utah. In the 2001 Warning Letter, without discussion with the Company of its written response to the 2001 FDA-483, Regina Barrell of the FDA Denver District Office demanded that UTMD hire an outside consultant to certify its quality system. Exercising its rights and confidence in its quality system, the Company respectfully declined. Four inspections of UTMD's Midvale facility ensued. Unable to reach closure without the benefit of any dialogue with agency personnel, in 2003 UTMD engaged a former District Director; Director, Division of Compliance Programs, CDRH; principal in the development and applications of regulations including the 1978 GMP Regulation and FDA Guidelines on the Principles of Process Validation; and 28-year veteran of the FDA; to review the documentation of the prior FDA inspections as well as conduct an independent investigation of UTMD's quality system. The resulting opinion states "that the investigators who conducted the inspection of the Utah Medical facility in February and March of 2003 engaged in inspectional practices in disregard of explicit instructions and policy stated in FDA's Investigations Operations Manual and prepared an Establishment Inspection Report (EIR) that contains numerous misrepresentations of the actual facts, bias, and material omissions.

These deficiencies create an impression about the company's compliance status that is at odds with the facts. If I had received such a report as the District Director of FDA's New England District, and, upon review, became aware of the extent of material omissions and misrepresentations, I would have disregarded the report in its entirety, and reprimanded the investigators for failure to follow FDA inspection policy. I believe the number and significance of deficiencies found in the EIR suggests the real possibility of agency misconduct and bias against Utah Medical Products, Inc."

The Midvale inspection in 1998 immediately prior to the 2001 inspection and warning letter was "clean" - classified as NAI (no enforcement action indicated) and no FDA FORM 483 was issued. This comprehensive inspection, conducted after FDA implementation of the current QSR, covered the same issues as the 2001 inspection. UTMD's manufacturing operations, documentation system and products have not significantly changed since the 1998 inspection. UTMD's Oregon facility specializing in injection molding operations, operating under the same quality system, was inspected in 1998 and again in 2004 without the issuance of a FDA-483.

UTMD's facilities have previously been certified under ISO 9001/EN 46001 quality standards since 1994. During 2003 UTMD was certified to compliance with the more stringent ISO 13485 standard applicable specifically to medical devices. The ISO standards are recognized throughout the world to reflect current quality system performance. These standards are issued by the most widely recognized international quality manufacturing standards organization and represent requirements applicable to approval in countries such as those of the European Union as part of the CE marking process.

UTMD is surprised that the FDA would issue a press release prior to any service of a Complaint on UTMD. UTMD advises that its devices are of state of the art quality preferred in particular by sophisticated clinician users, and that the FDA has never questioned the safety or effectiveness of its devices.

UTMD Chairman & CEO Kevin Cornwell expressed his reaction to the FDA effort by stating:

> "On behalf of the Directors, management, and employees of UTMD who have been and are dedicated to development and release of the safest and most effective devices possible, I am disappointed and bewildered by the performance of the FDA. We advise that the FDA has the burden to prove its allegations in the Courts of law, and regret that efforts by UTMD to engage in meaningful dialogue since 2001 have been repeatedly spurned. UTMD has offered to make any reasonable changes in our quality system that the FDA could identify, but they have refused to identify any changes or engage in any dialogue. Now, I believe it in the best interests of the company, the industry and the American public that the details of our dispute and the FDA's performance be fully discovered and publicly disclosed. To our clients throughout the world, I assure you that our continuing demonstration to satisfy their needs for our line of quality devices will not be affected."

UTMD devices have been used hundreds of thousands of times annually for many years in high risk birth and neonatal critical care situations with an extremely low frequency of complaints by any objective standards of measurement. Mr. Cornwell further expressed:

> "The confirmation of the success of manufacturing and quality procedures year after year is demonstrated by the excellent performance of our devices as used by skilled practitioners. UTMD builds its quality into its devices by carefully managing its activities through the performance of dedicated employees whose mission is not just to make devices but to make the best possible devices for mothers and babies as if each member of the public is a loved member of our family. We cannot concede to or tolerate conduct by the FDA that harms the public health through a misguided desire to cover up its mistakes and misuses public funds, abusing those who seek dialogue. UTMD requests that concerned industry members join us in our effort to assure that the FDA discharges its broad mandate fairly and objectively."

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.