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Changes to Medical Device Regulations in China

Significant Revisions to China's Regulations on the Supervision and Administration of Medical Devices (State Council Order No. 650)

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China's State Council released its new Administrative Regulation on the Supervision and Administration of Medical Devices March 7, 2014, which will be effective June 1, 2014 (the "New Regulation").

The State Council Legislative Affairs Office worked more than six years revising the predecessor of the New Regulation (the "Old Regulation"), which had been effective since 2000. The revisions are intended to establish a more efficient and scientific regulatory regime for supervision and administration of medical devices. The New Regulation addresses research and development, clinical trials, product approvals, manufacturing, business operations, sales, and advertising. Generally, the New Regulation moderates the oversight of low-risk medical devices and strengthens the supervision on high-risk devices. The New Regulation, summarized in our full client alert, will have a significant impact on all medical device enterprises.

Revised Administrative Measures on Medical Device Quality – CFDA Seeks Comments by June 15

On May 15, CFDA released its *Measures on the Supervision and Administration of the Quality of Medical Devices in Use* for public comment. Under the measures, medical device operators will be required to establish a quality management system especially for Class III devices. Features of this proposed system cover the purchase of medical devices, an incoming stock inspection and recording system, an inbound and outbound management system, a daily maintenance and recording system, a quality traceability recording system, a management system for disposable medical devices, and a management system for contracts and technical documents for products. **Comments are due to CFDA by June 15, 2014** at: 26 Xuanwumen West Street, Beijing, China 100053, and email: xuxy@sda.gov.cn. The weblink to this proposal is at: http://www.sfda.gov.cn/WS01/CL0779/99834.html

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