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ALERT

China Life Sciences

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China FDA Releases Guideline for Medical Device Registration Studies

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On May 19, 2015, the China Food and Drug Administration ("CFDA") unveiled the *Technical Guideline Governing Medical Device Clinical Evaluation* ("Guideline"). The long-awaited Guideline explains the methodology for clinical evaluation and elaborates the conditions for clinical study waivers under the 2014 revised Regulations on the *Supervision and Management of the Medical Devices* (also known as Order #650). Medical device manufacturers are advised to carefully review the Guideline and analyze the implications for their product registrations in China.

The Guideline governs the clinical evaluation of Class II and Class III devices (excluding in-vitro diagnostic reagents), a mandatory component of technical reviews under Order #650. The applicant is expected to demonstrate through a comprehensive evaluation of clinical literature, empirical data and clinical study data that (i) the device can achieve its intended function under normal conditions of use; (ii) the benefits of the device outweigh the risks; and (iii) the clinical performance and safety of the device are supported by adequate evidence.

Pursuant to the Guideline, a clinical study waiver is possible if the device under review is proven to be "equivalent" to a device listed in the CFDA's *List of Devices Exempted from Clinical Studies*. Alternatively, if the device under review is deemed "basically equivalent" to the same type of devices previously approved by the CFDA, the applicant can also waive the clinical study of its own device by using the clinical study and empirical data derived from the previously approved equivalent devices. Two devices are deemed "basically equivalent" if differences in their operating principles, structures, materials (for active devices, this applies to materials that come into contact with humans), production processes, safety evaluation, applicable national/industry standards, and intended use do not cause a negative impact on product safety and effectiveness.

With respect to the clinical study requirement for imported devices, the applicant may reference foreign study data, provided that (i) the study design meets CFDA's requirements for in-country registration studies (e.g., minimum sample size, selection of the control group, study end point, and outcome of therapeutic effects) and (ii) the applicants can present data showing no ethnicity differences. However, an in-country registration study on Chinese patients is mandatory for any devices listed in the *List of Class III Devices subject to Clinical Trial Approvals*.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang or your usual Ropes & Gray advisor.