CFDA Medical Device Regulation Updates

The new "***Regulations on Supervisory Management of Medical Devices***" have been approved by Premier, Li Keqiang on March 7th, 2014, and taken into effect upon June 1st, 2014. Then the CFDA (China Food and Drug Administration) issued Decree No.4, 5, 6, 7 and 8, and some other matching laws and regulations for the supervision of medical device.

Under the new policy system, supervision and management for the registration of medical device, manufacturing and business have arose significant change. It also brings new opportunities and challenges for you.

About the registration of medical device, the latest news of CFDA as below, please pay attention.

1. The Time Limit of Registration

A. Class Ⅰ medical devices are subject to the record by management

Record Items	First Record	Modification of Record
Time Limit (weekday)	Record on the spot	Record on the spot

B. Class Ⅱ and class Ⅲ medical devices shall be subject to management by registration

Administrative Licensing Items	First Registration		Registration Renewal		Modification of Approval Matters		Modification of Registration Matters	
Product Category	II	III	II	III	II	III	II	III
Acceptance	5		5		5		5	
Documents Forward	3		3		3		/	
Technical Evaluation	60	90	60	90	60	90	/	
Technical Reevaluation	60		60		60		/	
Administrative Decision	20		20		20		/	

Issue Certificate	10		10		10		10
Total Time Limit (not include the technical reevaluation)	98	128	98	128	98	128	15
Total Time Limit (include the technical reevaluation)	158	188	158	188	158	188	/

2. Registration fee: Unit: Yuan (RMB)

Project classification		Domestic	imported
Class Ⅱ	First registration fee	Specific rates shall be set by the financial departments in conjunction with the competent pricing department at the provincial level.	210,900
	Modification registration fee		4,200
	Renewal registration fee		4,080
Class Ⅲ	First registration fee	153,600	308,800
	Modification registration fee	5,040	5,040
	Renewal registration fee	4,080	4,080
	High risk medical device clinical trial approval fee	4,320	4,320

3. Significant Changes of Registration

Serial Number	**Significant changes of registration**
1	Class I medical devices are subject to the record by management, class II and class III medical devices shall be subject to management by registration.
2	Registration Renewal must at the time not later than six months prior to the expiration of the medical device registration certificate; apply to CFDA for renewal of registration, and submit the application documents in accordance with the relevant requirements.
3	Modification of registration includes approval matters and registration matters.
4	Renewal registration and modification of registration not permitted conduct at the same time.
5	The medical devices not in the clinical trial exemption catalog, the clinical trial must be conducted in China.
6	When the higher risk class Ⅲ medical devices conduct clinical trial should be approved by CFDA.
7	The "Product Technical Requirements" replace the "Registered Product Standard".