CFDA Regulatory Process for Medical Devices

Identify the medical device classifacation.

Class I	Class II	Class III
	Identify predicates & determine the clinical data requirements.	
Demonstrate proof of home country approval.		
Submit a notarized "proof of qualification of the manufacturer."		
Prepare "Product Technical Requirement" document. Include details of testing to be conducted in China. Compile application dossier.*		
	Send devices to China for testing to be carried out by a CFDA authorized Medical Device Evaluation Center. Prepare China Clinical Evaluation.	
Prepare technical documentation in Simplified Chinese & submit to CFDA. No fees.	Prepare registration dossier including testing reports, Agent authorization letter, CFS/CFG, clinical evaluation** (if applicable), and other technical documents in Simplified Chinese. Then submit to CFDA for review. Pay fees.	
Undergo an Administrative review.	Have a full application review conducted, including a technical and administrative review. Novel and high-risk products may also be subject to an Expert Panel Meeting. CFDA has the option to conduct on-site QMS audit of foreign manufacturers.	
CFDA issues Class I voucher and publishes on website.	CFDA issues registration certificate and posts online. Certificates are valid for 5 years. You must place your CFDA license number on your device labeling, including IFU.	

* Foreign test reports are generally accepted for Class I devices; Class II and III devices require a combination of foreign and local test reports.
** The CFDA requires a Clinical Evaluation for all Class II and III devices, unless exempted. The China Clinical Evaluation is unique and requires comprehensive comparison to an equivalent product already approved in China, where available. It differs significantly from a CER submitted for European CE Marking.

Device Classification in China	Class I	Class II	Class III
How long you should expect to wait after submission until approval is tranted	<1 week	12-20 months	12-22 months
Validity period for device registrations	Doesn't expire	5 years	5 years
Registration renewal should be started this far in advance	Not appicable	18-24 months	18-24 months
Complexity of the registration process for this classification	Simple 1 2 3 4 5 Complex	Simple 1 2 3 4 5 Complex	Simple 1 2 3 4 5 Complex
Overall cost of gaining regulatory approval	Low 1 2 3 4 5 High	Low 1 2 3 4 5 High	Low 1 2 3 4 5 High