

# 510k Bridge

## Service Overview & Capabilities

### WHO WE SERVE

Chinese medical device companies seeking FDA 510(k) clearance to enter the US market. We specialize in Class II non-invasive devices: patient monitors, imaging systems, rehabilitation equipment, diagnostic tools, and software-as-a-medical-device (SaMD).

### THE PROBLEM

- Language & regulatory culture gap between NMPA and FDA processes
- No visibility into project status across distributed teams (China + US)
- Difficulty coordinating testing labs, US agents, and regulatory consultants
- High failure rates: ~30% of 510(k) submissions receive AI requests
- Costly delays from preventable errors (wrong predicate, missing test data, RTA)

### OUR SOLUTION

A bilingual (EN/CN) 510(k) project management platform paired with experienced regulatory professionals. From strategy through clearance, we bridge the language, process, and compliance gap.

### PLATFORM HIGHLIGHTS

- 15-tab Control Tower dashboard
- Bilingual 9-step setup wizard
- Dual-track milestone tracking
- FDA Communications Center
- Q-Sub generation automation
- Document control with version history
- Risk & budget monitoring
- Thread-based team messaging (EN/CN)
- Automated RTA self-check
- Data Source Ref for audit traceability

### BY THE NUMBERS

**12-18 mo**

Typical clearance timeline

**90-120 days**

Average FDA review period

**\$150K-\$400K**

End-to-end budget range

### SERVICE TIERS

#### SaaS Platform From \$500/mo

- Control Tower dashboard
- Bilingual setup wizard
- Dual-track milestones
- Document control
- Team messaging
- Risk & budget tracking

#### Professional PM \$10-25K/mo

- All SaaS features
- Dedicated PMP project manager
- FDA Comms Center
- US Agent representation
- Gate review management
- Submission oversight
- Supplier coordination

#### Enterprise Project-Based

- All Professional features
- End-to-end 510(k) management
- Regulatory strategy
- RTA self-check & DHF readiness
- US Agent representation
- US entity formation
- Investor documentation

### GET STARTED

[info@510kbridge.com](mailto:info@510kbridge.com) | [510kbridge.com](https://510kbridge.com) | Schedule a free consultation today.