

510(k) Pathway Guide

For Chinese Medical Device Companies
Entering the US Market

Presented by 510k Bridge

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This guide provides a practical overview of the FDA 510(k) clearance pathway for Chinese medical device companies. It covers key concepts, timelines, common pitfalls, and strategic recommendations to help you plan your US market entry successfully.

1. Is 510(k) Right for You?

The FDA classifies medical devices into three classes based on risk. Your regulatory pathway depends on your device classification:

Class I	Low risk (e.g., bandages, tongue depressors). Most are exempt from 510(k). Simple registration.
Class II	Moderate risk (e.g., powered wheelchairs, infusion pumps, patient monitors). Most require 510(k) clearance by demonstrating 'substantial equivalence' to a predicate device.
Class III	High risk (e.g., implantable pacemakers, heart valves). Requires Pre-Market Approval (PMA) -- a much longer and more expensive process.

Most Chinese medical device companies entering the US market have Class II devices. If your device is Class II, the 510(k) pathway is almost certainly the right choice.

How to Confirm Your Classification

Steps to verify your device's FDA classification:

- Search the FDA Product Classification Database (accessdata.fda.gov)
- Identify your device's product code (e.g., IKN for sEMG, DQS for EIT)
- Check the regulation number and classification panel
- If uncertain, submit a Pre-Submission (Q-Sub) request to FDA for guidance

2. The 510(k) Timeline: What to Expect

A realistic 510(k) timeline for a non-invasive Class II device is 12-18 months from project start to FDA clearance. Here is a typical breakdown:

Months 0-2	Regulatory Strategy: Identify predicates, product codes, and applicable standards. Prepare and submit the Pre-Submission (Q-Sub) request to FDA.
Months 2-4	FDA Pre-Sub Meeting: Receive FDA feedback on your testing strategy, predicate selection, and intended use statement.
Months 3-8	Design Controls & Testing: Complete bench testing, biocompatibility (if applicable), software validation, electrical safety (IEC 60601), and EMC testing.
Months 6-10	Clinical Evidence: Compile clinical data -- literature review, bench study reports, and/or clinical studies (often not required for non-invasive devices).
Months 10-13	Submission Preparation: Compile the 510(k) package including performance data, substantial equivalence arguments, labeling, and software documentation.
Months 13-18	FDA Review: Submit to FDA. Respond to any Additional Information (AI) requests. Average review time is 90-120 days for a traditional 510(k).

Key insight: The Pre-Submission meeting (Q-Sub) at months 2-4 is the single most important step. It lets you align with FDA before investing in expensive testing.

3. Pre-Submission Strategy: Engage FDA Early

A Pre-Submission (Q-Sub) is a formal request to meet with FDA and discuss your regulatory strategy before filing the actual 510(k). It is optional but strongly recommended -- especially for first-time submissions from companies new to the US market.

What to Include in Your Q-Sub

- Device description and intended use
- Proposed predicate device(s) with substantial equivalence rationale
- Proposed testing plan (bench, biocompatibility, clinical)
- Specific questions for FDA (e.g., 'Is this predicate acceptable?', 'Do you agree with our testing approach?')

Q-Sub Process

- Submit the Q-Sub package to CDRH (Center for Devices and Radiological Health)
- FDA sends a response letter within 75 days (often with written answers)
- If a meeting is requested, it typically occurs at day 70-75
- The meeting is teleconference-based (no need to travel to the US)

Benefits

- Reduces risk of RTA (Refuse to Accept) on your actual submission
- Confirms that your predicate selection is acceptable to FDA
- Identifies any testing gaps before you invest in expensive lab work
- Creates an FDA record that demonstrates proactive regulatory engagement

4. Key Regulatory Standards

FDA expects Class II devices to comply with recognized consensus standards. The specific standards depend on your device type, but most non-invasive medical electrical equipment needs the following:

IEC 60601-1	General requirements for basic safety and essential performance of medical electrical equipment. This is the foundation standard.
IEC 60601-1-2	Electromagnetic compatibility (EMC) -- immunity and emissions testing. Essential for any device with electronic components.
ISO 14971	Risk management. Required for all medical devices. Demonstrates systematic identification and mitigation of hazards.
IEC 62304	Software lifecycle processes. Required if your device contains software (standalone or embedded). Defines software development class (A, B, or C) based on risk.
ISO 10993	Biocompatibility testing. Required if any component contacts the patient. Non-invasive surface-contact devices typically need a subset of tests.
IEC 62366-1	Usability engineering. Demonstrates that the user interface is safe and effective through formative and summative usability studies.

Tip: You do not need to test against every standard on the FDA list. The Q-Sub meeting (Section 3) helps you identify exactly which standards FDA expects for your specific device.

5. Common Pitfalls & How to Avoid Them

5.1 RTA (Refuse to Accept)

FDA screens every 510(k) submission within 15 days of receipt using an RTA checklist. If critical elements are missing, the submission is refused before substantive review even begins. Common RTA triggers:

- Missing or incomplete Indications for Use statement
- Inadequate predicate comparison (technological characteristics)
- Missing software documentation (if applicable)
- Incomplete performance testing summaries
- Labeling deficiencies

5.2 Predicate Selection Errors

Choosing the wrong predicate device is one of the most expensive mistakes:

- Predicate must have the same intended use as your device
- Technological differences must not raise new safety or effectiveness questions
- Avoid 'predicate creep' -- chaining through multiple predicates weakens your argument
- FDA may disagree with your predicate -- the Q-Sub resolves this early

5.3 Testing Gaps

Insufficient test data is the #1 reason for Additional Information (AI) requests:

- Ensure bench testing matches the testing plan discussed in the Q-Sub
- Software validation must follow IEC 62304 classification rigor
- EMC testing must use the latest IEC 60601-1-2 edition
- If clinical data is needed, start early -- clinical studies add 6-12 months

5.4 Translation & Cultural Gaps

FDA submissions must be in English. Technical accuracy in translation is critical -- mistranslated terminology can cause rejection or misunderstanding. Work with a regulatory team that is fluent in both languages and FDA terminology.

6. US Entity Requirements

To sell a medical device in the United States, your company must meet several establishment and registration requirements:

6.1 FDA Establishment Registration

- Every establishment that manufactures, distributes, or imports medical devices must register with FDA annually
- Registration is done through the FDA Unified Registration and Listing System (FURLS)
- A US Agent must be designated if the manufacturer is located outside the US

6.2 US Agent

- Required for all foreign manufacturers selling into the US market
- The US Agent acts as the FDA's point of contact for your company
- Must be located in the United States and available during business hours
- Can be a company or individual -- several firms specialize in this service

6.3 Device Listing

- Each device must be listed with FDA, including product code and device class
- Listing must be updated when devices are added, removed, or modified

6.4 US Entity Formation (Optional)

While not required by FDA, many Chinese companies form a US subsidiary (typically a Delaware LLC or C-Corp) for business, legal, and investor-relations purposes. This simplifies contracts, banking, and demonstrates commitment to the US market.

7. Cost Planning

Budget planning is essential. Here are typical cost ranges for a Class II non-invasive 510(k) submission (all figures in USD):

FDA User Fee	\$22,000-\$23,000 (standard 510(k), updated annually; small business exemptions may apply)
Testing (IEC 60601)	\$30,000-\$80,000 depending on device complexity and number of applicable particular standards
EMC Testing	\$15,000-\$30,000 for IEC 60601-1-2 compliance
Software (IEC 62304)	\$10,000-\$40,000 for documentation and validation, depending on software safety class
Biocompatibility	\$10,000-\$50,000 depending on patient-contact characterization
Regulatory Consulting	\$50,000-\$150,000 for end-to-end project management, strategy, submission preparation, and FDA liaison
US Agent	\$3,000-\$6,000 per year
US Entity Formation	\$2,000-\$5,000 (one-time, if applicable)

Total budget: Plan for \$150,000-\$400,000 for a typical Class II 510(k) submission. The largest variable is testing -- the Q-Sub meeting helps define exactly what testing is needed, so you avoid over-testing or under-testing.

8. How 510k Bridge Can Help

510k Bridge specializes in helping Chinese medical device companies navigate the FDA 510(k) process. Our bilingual team bridges the language, regulatory, and business culture gap between China and the US market.

Control Tower License -- From \$500/mo

- Dedicated project dashboard with 15-tab Control Tower platform
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- US Agent representation (required for all foreign manufacturers)
- Gate review management and regulatory submission oversight
- Supplier coordination and stakeholder management

Enterprise -- Project-Based Pricing

- Everything in Professional, plus end-to-end 510(k) management
- Regulatory strategy and pathway development
- Automated RTA self-check and DHF readiness assessment
- US Agent representation (required for all foreign manufacturers)
- US entity formation assistance
- Investor-ready documentation

Ready to start your 510(k) journey?

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Schedule a free consultation today.