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Add value.**

FDA 510(K)

Your Key into the US Market
您进入美国市场的钥匙

TÜV SÜD Group

TÜV®



Understanding market entry requirements

The ever increasing demand for medical devices all over the world has presented excellent opportunities to device manufacturers. However, compliance with local regulations, standards and market entry requirements are a must in order to enter the corresponding markets.

How to enter the U.S. Medical Device Market ?

Manufacturers who want to sell medical device intended for human use and for in vitro diagnosis in the U.S. are required to apply to the FDA. According to medical device classification database published by the FDA, some of Class I, most of Class II and few of Class III devices are required to submit 510(K) to FDA for review to get U.S. market clearance.

What is FDA 510(K)?

- Premarket Notification, Section 510(K), Federal Food, Drug, and Cosmetic Act;
- Documents for demonstrating substantial equivalence in premarket notifications comparing to predicate devices which are already legally marketed in the U.S.

When must we Submit a 510(K)?

- When introducing a device into commercial distribution (marketing) to U.S. market for the first time;
- When a different intended use is proposed for a device already in legally marketed;
- When there is a change or modification of a legally marketed device (for instance, modification of design or materials) and that change could significantly affect its safety or effectiveness.

了解市场准入要求

世界范围内对医疗器械需求量的不断增大，为众多医疗器械制造商提供了极好机遇。但想进入相关市场，就必须遵循相应的法令、法规和标准，遵守产品在不同市场准入的规定。

如何进入美国医疗器械市场？

对于用于人体的医疗器械及体外诊断器械，要在美国市场销售，需要向美国食品与药品管理局 (FDA) 提交相关申请文件并通过FDA 审核。根据FDA 产品代码数据库，I类器械中的少部分产品、II类器械中的大部分产品和个别III类产品，需要通过510(K)的途径进入美国市场。

什么是 FDA 510(K)？

- 上市前通告，见食品，药品和化妆品法案第510(K) 章节；
- 参照已在美国合法上市的器械进行实质性等同说明的一套文件。

什么时候需呈交510(K)？

- 器械首次投放美国市场时；
- 上市器械更改预期用途时；
- 上市器械作出重大更改时；
(如修改设计、材料等，导致产品安全有效性受到影响)。



Benefits of choosing TÜV SÜD for Third Party Review

- A FDA-authorized third party qualified to conduct 510(K) review of Class I and Class II medical devices in the U.S. market;
- Shorten the review cycle and lead time;
- TÜV SÜD recommendation letters will be responded by FDA within 30 days with K number;
- Fast and convenient local support;
- Dedicated account and technical team on the ground, providing professional, convenient, timely and efficient services for medical device compliance to FDA regulations.

TÜV SÜD Services

- Training on FDA 510(K) regulations and processes;
- Reviewing FDA 510(K) submission files, provide review result report for submission;
- Providing recommendation letter to the FDA;
- Introducing authorized representative in U.S. market.

Post-market surveillance in the U.S.

As there is an increasing number of medical devices being exported from China to the U.S., factory inspections by FDA inspectors of Chinese manufacturers are becoming more common.

The auditors from TÜV SÜD China have received official training on FDA 21CFR820, and have attended many FDA factory inspections, they are provided with substantial resources, and are highly experienced to serving Chinese manufacturers.

选择TÜV 南德意志集团第三方评审的优势:

- TÜV 南德意志集团是FDA授权认可的510(K) 第三方审查机构, 有权对美国 I类、II类医疗器械的510(K) 进行评审;
- 缩短审查周期, 加快新产品上市步伐;
- 作为第三方评审的权威公告机构, TÜV 南德意志集团提供的推荐信, FDA 将在30天内优先做出反应, 并提供K号;
- 快速便捷的本地化服务;
- TÜV 南德意志集团成立FDA专业小组, 强大的国内技术人力资源确保在该领域为医疗器械厂商提供更专业、迅捷、及时、有效的服务。

TÜV 南德意志集团提供的服务

- 为客户提供相关FDA 510(K) 法规及流程的培训;
- 对FDA 510(K) 申请文件进行评审, 提供评审结果报告;
- 向FDA提供推荐信;
- 介绍美国市场授权代表。

产品在美国上市后之跟进

随着越来越多的来自中国的医疗器械销往美国市场, 中国企业经历FDA专职检查员进行工厂检查的几率越来越高。

TÜV 南德意志集团的审核员已接受了有关FDA 21CFR820的正式培训, 并参加过多次FDA的现场审核, 拥有强大的资源和经验为中国企业提供服务。



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TÜV SÜD Services

- Mock inspection for manufacturers according to QSR after FDA 510(K) clearance;
- Provide QSR training for manufacturers.

TÜV 南德意志集团提供的服务

- 为企业在FDA 510(K)注册后，按照质量体系法规QSR进行模拟工厂检查；
- 为企业提供美国QSR质量体系法规培训。

About TÜV SÜD

Established in Germany 140 years ago, TÜV SÜD is one of the world's leading technical services providers, offering knowledge services, inspections, testing, expert opinions, certification and training. Approximately 16,000 employees at over 600 locations worldwide provide technology, system and know-how optimization.

TÜV 南德意志集团简介

140年前诞生于德国，TÜV 南德意志集团是业内领先的技术服务公司，为您提供资讯，检验，测试，专家意见，认证和培训服务。16,000多名员工遍及全球600多个办事处，着力为您实现技术、体系和实际运作中的优化服务。

For one stop German expertise in Greater China, please contact one of our branch offices, sales offices or representative offices:

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