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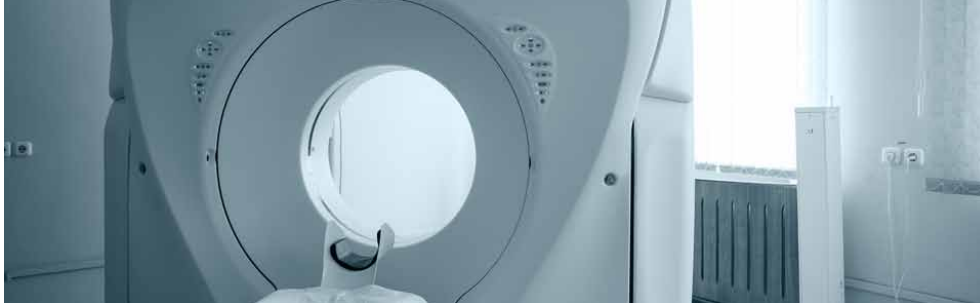
A close-up, blue-tinted photograph of a stethoscope resting on a reflective surface. The stethoscope is the central focus, with its chest piece and tubing clearly visible. The background is a soft, out-of-focus blue.

FDA 510(K), Your Key into
the US Market

FDA 510(K), 您进入美国市场
的钥匙

TÜV SÜD China

TÜV®



If you want to survive in today's medical device market, never ever ignore the US Market...?

The ever increasing demands for medical devices all over the world have presented excellent opportunities to the device manufacturers. However, compliance with local regulations, standards and market entry requirement is a must to enter the corresponding market.

How to Enter 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 FDA. According to medical device classification database published by 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 U.S.A.

Who is Required to Submit a 510(K)?

- Introducing a device into commercial distribution (marketing) to U.S. market for the first time;
- A different intended use is proposed for a device already in legally marketed;
- 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.

如果您要在今日的医疗器械市场发展壮大，忽视美国市场？绝不容许…

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。

哪些企业需呈交 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 the Third Party Review by TÜV SÜD

- TÜV SÜD is a FDA authorized third party who is qualified for review 510(K) of Class I and class II medical devices in U.S. market.
- Shorten review cycle and lead time
- FDA will give response to recommendation letters by TÜV SÜD within 30 days, and provide K number.
- Fast and convenient localized services
- A dedicated FDA group has been set up by TÜV SÜD China to provide, with strong domestic technical staff, more professional, convenient, timely and efficient services for medical device manufacturers.

TÜV SÜD Services

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

Post-market surveillance in U.S.

As there are an increasing number of medical devices exported from China to U.S.A., factory inspection by FDA inspector at Chinese manufacturers has become more and more frequent and common.

The auditors from TÜV SÜD China have received official training on FDA 21CFR820, and have attended FDA factory inspection for many time, who are provided with powerful resources and experiences to serve Chinese manufacturers.

TÜV SÜD Services

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

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。



www.tuv-sud.cn

For one-stop German expertise in Greater China, please contact one of these major offices:

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