医疗器械欧盟CE认证技术文件与美国FDA认证510（k）之间的差别

产品名称	医疗器械欧盟CE认证技术文件与美国FDA认证510（k）之间的差别
公司名称	国瑞中安集团-实验室
价格	.00/件
规格参数	
公司地址	深圳市光明区凤凰街道塘家社区光明高新产业园2号楼1层
联系电话	15815880040 15815880040

产品详情

欧盟CE认证技术文件与美国FDA认证510（k）之间的差别：

欧盟和美国公司有义务条件有足够的技术文件证明监管机构应检查和确定安全水平，在欧盟，术语“ 技术文件 ”用于描述为I类，IIa类和IIb类产品编译的文件，III类产品有一个不同的技术文件叫做：DesignDossier。

相当于美国的技术文件：

1.510（k）>用于与市场上已有的产品相似的产品

2.PMA应用>这是III类和高风险II类设备所必需的。

在技术文件中，欧盟条件以比FDA条件更详细，更有条理和更具体的方式组织文件，在附件I中，MDD提出了确定zui低安全考虑因素的基本条件。这些基本条件是可能影响医疗器械安全的因素清单，例如设计，构造，包装和标签。

对于每个适用的基本条件，技术文件还必须包括欧洲标准（EN）协调标准和用于证明符合EN标准的其他标准。已经制定了统一的安全标准，以提供证明符合相关指令的途径。适用于医疗器械的数百种EN协调标准;其中一些适用于影响各种设备的广泛定义的因素（例如，风险评估，包装，标签和说明），而其他因素适用于更具体的领域（例如，γ或环氧乙烷灭菌）。如果没有适用的欧洲标准，可以援引其他标准，如国家标准或国际 标准。

技术文件还必须包括声称符合标准或标准中适用条款的证据-
例如，风险分析结果，测试结果，安全报告，临床试验数据，与其他产品的等效性。

好消息是，FDA已经增加了所需的信息范围，包括技术和安全标准，风险分析。因此，zui近开发出全面的510（k）和PMA应用的公司应满足大多数欧盟条件。然而，对于年龄较大的510（k），情况则不同，当510（k）szui初创建时，它们通常缺乏欧盟现在需要的那种技术文档。

质量 保证

美国医疗设备制造商在无菌设备的质量体系条件方面面临更大的挑战，然后是非无菌设备，欧盟条件公司控制制造和包装环境，以实现绝育，而不会过量使用化学品。FDA对灭菌采取了更为宽松的观点，允许更高水平的灭菌剂。

无菌和非无菌设备

简单的FDAI类非无菌设备应该能够满足欧盟85%的条件，欧盟和美国条件之间的差异是欧盟标签和使用的多个翻译。虽然这是一个微小的变化，但翻译可能是一个重大问题。如果公司想要在所有15个欧盟国家/地区销售设备，则可能需要使用12种语言标记翻译。

Differences between EU CE certification technical documents and US FDA certification 510 (k):

European and American companies are obliged to provide sufficient technical documents to prove that the regulatory authority should check and determine the safety level. In the European Union, the term "technical document" is used to describe the documents compiled for Class I, IIa and IIb products. There is a different technical document for Class III products called DesignDossier.

Technical documents equivalent to the United States:

1.510 (k)>For products similar to those already on the market

2. PMA application>This is necessary for Class III and high-risk Class II equipment.

In technical documents, EU conditions organize documents in a more detailed, organized and specific way than FDA conditions. In Annex I, MDD puts forward the basic conditions for determining the minimum safety considerations. These basic conditions are a list of factors that may affect the safety of medical devices, such as design, construction, packaging and labeling.

For each applicable basic condition, the technical documents must also include European Standard (EN) harmonized standards and other standards used to prove compliance with EN standards. Uniform safety standards have been developed to provide a means of demonstrating compliance with the relevant directives. Hundreds of EN harmonized standards applicable to medical devices; Some of these apply to broadly defined factors that affect various equipment (e.g., risk assessment, packaging, labelling and instructions), while others apply to more specific areas (e.g, γ Or ethylene oxide sterilization). If there is no applicable European standard, other standards, such as national standards or international standards, can be cited.

The technical documents must also include evidence claiming compliance with the standards or applicable clauses in the standards - for example, risk analysis results, test results, safety reports, clinical trial data, and equivalence with other products.

The good news is that FDA has increased the scope of information needed, including technical and safety standards, and risk analysis. Therefore, companies that have recently developed comprehensive 510 (k) and PMA applications should meet most EU conditions. However, the situation is different for the older 510 (k) s. When 510 (k) s were

originally created, they usually lacked the kind of technical documents that the EU now needs.

quality assurance

American medical equipment manufacturers face greater challenges in terms of the quality system conditions of sterile equipment, followed by non sterile equipment. European Union Condition Company controls the manufacturing and packaging environment to achieve sterilization without excessive use of chemicals. FDA has taken a more relaxed view on sterilization, allowing higher levels of sterilization agents.

Sterile and non sterile equipment

Simple FDAI type non sterile equipment should be able to meet 85% of the conditions in the EU. The difference between EU and US conditions is the multiple translations of EU labels and use. Although this is a minor change, translation may be a major issue. If the company wants to sell equipment in all 15 EU countries, it may need to use 12 language mark translations.