# HCG试纸办理美国US Agent FDA510K注册

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| 产品名称 | HCG试纸办理美国US Agent FDA510K注册 |
| 公司名称 | 上海沙格医疗科技有限公司 |
| 价格 | .00/件 |
| 规格参数 | 服务范围:全国<br>价格:根据产品报价<br>报告是否官网可查:是 |
| 公司地址 | 上海市崇明区长兴镇潘园公路2528号B幢21031室 |
| 联系电话 | 15001902415 15001902415 |

# 产品详情

在欧盟将轮椅车推向市场之前，必须符合欧盟法规（EU）2017/745中的必要要求。该法规涵盖了各样的产品，根据附录Ⅷ中的分类规则，轮椅车和代步车均被归类为Ⅰ类。化妆品FDA注册 FDA化妆品注册 1/ 化妆品企业注册可以在出口美国之前或者出口之后（30天内）；2/ 化妆品产品注册需要有1000美金的出口之后，但是实际上FDA无法核对；3/ Can I file formulations in the VCRP for products that are considered drugs but also have a cosmetic function? 对于药品有化妆品功能的是否可以做化妆品注册？ Yes, products that are considered drugs in the United States, such as sunscreens, but also make cosmetic type claims, such as moisturizing, can be filed in the VCRP. 4/ 可以进行化妆品注册，但是这并不能豁免其需要同时满足药品的相关要求的职责。 办理化妆品的FDA相对来说比较简单，企业提供企业信息以及产品成分表（中英文）就可以了。510(K)审查程序 FDA在收到企业递交的510(k)资料后，先检查资料是否，如资料，则受理并给企业发出确认性，同时给出申请受理编号(K YYXXXX)，此号码也将作为正式批准后的号码;如不，则要求企业在规定时间内补充，否则作企业放弃处理。FDA在受理申请后即进入内部工作程序，其中可能还会要求企业补充一些资料。在510(k)申请通过审阅后，FDA并不立即发出批准函件，而是根据产品风险等级、市场先前是否对企业有不良反 映等确定是否对企业进行现场GMP考核，考核通过后再发给企业正式批准函件(Clearance);如无须现场考核GMP，则510(k)申请通过后立即发给正式批准函件。每年更新FDA 要求：1) 注册和登记每年要更新一次（更新时间是：10月1号到12月31号 2) 要随时通知FDA注册和登记内容的变化。 – II 类产品，在进行设施登记和器械注册后，还需递交“ 上市前通知 ”即510(K)申请。只有个别产品510(K) 豁免。Responsibilities of a U.S. agent The U.S. agent must either reside in the U.S. or maintain a place of business in the U.S. The U.S. agent cannot use a post office box as an address. The U.S. agent cannot use an answering service. They must be available to answer the phone or have an employee available to answer the phone during normal business hours. The responsibilities of the U.S. agent are limited and include: assisting FDA in communications with the foreign establishment, responding to questions concerning the foreign establishment's devices that are imported or offered for import into the United States, assisting FDA in scheduling inspections of the foreign establishment and if FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the U.S. agent, and such an action shall be

considered to be equivalent to providing the same information or documents to the foreign establishment. Please note that the U.S. agent has no responsibility related to reporting of adverse events under the Medical Device Reporting regulation (21 CFR Part 803), or submitting 510(k) Premarket Notifications (21 CFR Part 807, Subpart E).