

产品发生哪些变更需要重新申请510(K)

产品名称	产品发生哪些变更需要重新申请510(K)
公司名称	深圳市思博达管理咨询有限公司
价格	.00/件
规格参数	
公司地址	深圳市宝安区西乡大道780号万骏汇大厦1212
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产品详情

以下产品变更需要重新申请510(K)

A change in indications for use from prescription use to over the counter use

Addition of a new patient population

Changes to the environment of use such as from professional use to home use or hospital use to ambulatory transport

Changes in frequency or duration of use

Change to indicate compatibility with a type of device, component, or accessory that was not indicated as compatible with the previously cleared device

Changes in sterilization, cleaning or disinfection

Changes in package integrity or shelf-life claims

Changes in device design

Changes to employ wireless communication

Changes in the human factors of the patient or user interface

A change in material type, formulation or chemical composition

Changes in the antibody, detection reagents, critical reaction components or conjugates for in vitro diagnostic (IVD) devices

