

附件 1

医疗器械召回事件报告表

提交: 企业所在地省级食品药品监督管理部门 器械注册/备案部门

产品名称	胎儿/孕妇监护仪	注册证或备案 凭证编码	粤械注准 20172211780
生产企业名称	飞利浦金科威 (深圳) 实业有限公司		
代理人名称	/		
召回单位负责人和联系方式, 经办人和联系方式	飞利浦金科威 (深圳) 实业有限公司 负责人: 李萍 0755-86278175 经办人: 岳凤琼 0755-86278175		
产品的适用范围	供医疗机构对胎儿的心率和胎动以及宫缩压力进行监测, 对孕妇的无创血压、脉率、血氧饱和度、心电、心率参数进行监测。		
涉及地区和国家	中国	召回级别	二级
涉及产品生产 (或进口中国) 批次、数量	5053	涉及产品 型号、规格	CTG7
识别信息 (如批号)	见附表	涉及产品在 中国的销售数量	2712
召回原因简述	公司在其他产品上发现, 该胎儿/孕妇监护仪配套使用的锂电池, 在超过使用年限后可能会发生过热或燃烧的情况。这些电池应在容量小于 80% 或者充放电 300 次以后 (以先到者为准) 进行更换; CTG7 产品迄今为止没有发生同类问题, 但为预防该问题可能发生, 公司决定召回可能受影响设备进行软件升级。 本次升级软件将更方便用户管理电池生命周期的充放循环次数和健康状态, 并提供可视性报警提醒用户适时更换电池。		
纠正行动简述 (包括召回要求和处理方式等)	发布服务指南, 增加电池管理以及更换的信息。 进行软件升级, 增加用户提示, 使用户对电池寿命的管理更便捷。		

报告单位: (盖章)

报告人: (签字)



负责人: (签字) 李萍

报告日期: 2019年11月15日

涉及的产品序列号:

粤械注准 20172211780 中国境内召回的 2712 台产品序列号 SN:

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