

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

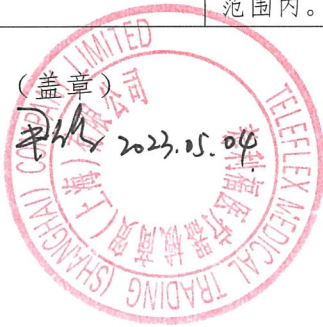
■器械注册/备案部门

产品名称	主动脉内球囊反搏泵 Intra-Aortic Balloon Pump System	注册证或备案 凭证编码	国械注进 20203080452 国械注进 20153081603 国械注进 20153211603 国食药监械(进)字 2011 第 3211652 号
生产企业名称	Arrow International LLC/Arrow International Inc. 箭牌国际公司		
代理人名称	泰利福医疗器械商贸(上海)有限公司		
召回单位负责人和联系方式, 经办人和联系方式	负责人: 陆仙娟 021-60606980, 159 2157 9712 经办人: 尹玲 021-60606981, 138 1856 9759		
产品的适用范围	该产品临床适用于成年患者的主动脉内球囊反搏治疗。		
涉及地区和国家	澳大利亚;孟加拉国; 文莱;中国;厄瓜多尔; 印度;印度尼西亚;日 本;韩国;马来西亚;蒙 古;缅甸;尼泊尔;新西 兰;巴勒斯坦;菲律宾; 新加坡;斯里兰卡;越 南	召回级别	一级召回
涉及产品生产(或进口中国) 批次、数量	批次: 见附件 数量: 1845(台)	涉及产品 型号、规格	IAP-0400, IAP-0500, IAP-0601, IAP-0701
识别信息 (如批号)	见附件	涉及产品在 中国的销售数量	1831(台)
召回原因简述	Arrow 主动脉内球囊反搏泵可通过连接至网电源供电或在网电源断电的情况下通过电池紧急供电。当使用电池电源运行该设备时, 电池满电状态下, 设备预期持续运行时间为 90 分钟。最近, 生产商收到的客户投诉报告, 一些使用该设备的用户发现电池紧急供电状态下设备运行时间缩短的情况。在过去两年里, 生产商收到 1 例关于该设备在没有出现电池续航剩余时间警报而突然断电的客		

	<p>户投诉；13例关于该设备警报发出的时间间隔短于警报指示值的客户投诉。截至2023年03月21日，生产商未发现任何与电池续航时间相关的患者伤害或死亡。同时，到目前为止，我司在中国大陆范围内未收到任何与电池续航时间相关的客户投诉和不良事件。</p> <p>此召回为2022年上报的召回的范围扩展，进口新增99台。</p>
<p>纠正行动简述（包括召回要求和处理方式等）</p>	<p>针对上述情况，泰利福医疗器械商贸(上海)有限公司采取如下措施：</p> <ol style="list-style-type: none"> 1. 自2022年11月18日起仍在泰利福仓库的产品，随附客户告知信与用户操作手册给受影响的客户，后续无需再发送客户通知。 2. 至2022年11月18日已销售的产品，则发送客户告知信给客户，客户无需返回产品，根据客户告知信的提示信息继续使用相关产品。 3. 通过此现场安全措施，使产品这类风险控制公司的风险控制范围内。

报告单位：（盖章）

报告人：



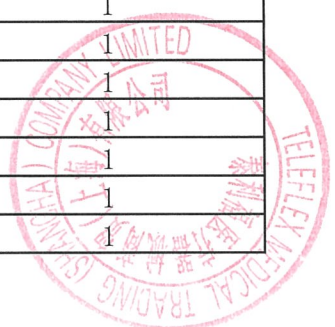
负责人：

报告日期：

陆仕明
2023.05.04

附件一

涉及产品型号规格	识别信息（序列号）	进口中国数量（台）	在中国销售数量（台）
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如下为新增清单（如下产品已在泰利福仓库分销前随附客户告知信）：

涉及产品型号规格	识别信息（序列号）	进口中国数量（台）	在中国销售数量（台）
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