

附件 1

医疗器械召回事件报告表

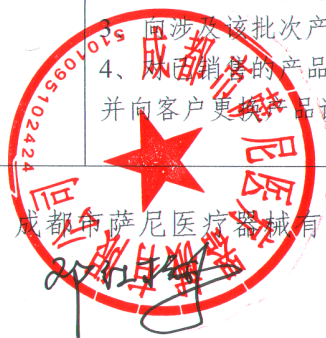
提交: 企业所在地省级食品药品监督管理部门

器械注册/备案部门

产品名称	根管预备机	注册证或备案凭证编码	川械注准 20172550151
生产企业名称	成都市萨尼医疗器械有限公司		
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	负责人: 何春霞 13608220669 经办人: 邓红梅 13699004540		
产品的适用范围	产品适用于根管治疗中根管预备阶段成形和清理, 不含牙根尖定位功能(或叫做根管长度测量功能)。		
涉及地区和国家	中国	召回级别	三级
涉及产品生产(或进口中国)批次、数量	生产批次: 详见附页 数量: 4785 台	涉及产品型号、规格	SN-SMART-I
识别信息(如批号)	详见附页	涉及产品在中国的销售数量	4785 台
召回原因简述	根管预备机使用红色指示灯作为充电状态指示, 不符合 GB9706.1-2007 6.7 的要求。该缺陷不影响使用性能, 不会引起伤害, 到目前为止未收到任何因为该指示灯而引起的投诉或不良事件, 但为符合标准要求, 我司主动采取纠正改善措施。		
纠正行动简述(包括召回要求和处理方式等)	1、产品内部设计变更, 将红色指示灯改为橙色, 并委托四川省医疗器械检测中心进行检测; 2、向四川省药品监督管理局申请注册变更(产品技术要求变更)和说明书备案变更; 3、向涉及该批次产品销售、使用的经销商和用户发布召回通知; 4、对已销售的产品安排工程师上门处理, 更换充电指示灯的颜色, 并向客户更换产品说明书。		

报告单位: (盖章) 成都市萨尼医疗器械有限公司
 报告人: (签字)

负责人: (签字)
 报告日期: 2021.7.7



产品编号	产品编号	产品编号	产品编号	产品编号
2017062899 (SN)	2017062788 (SN)	2017062953 (SN)	2017062848 (SN)	2017063017 (SN)
2017062901 (SN)	2017062789 (SN)	2017062954 (SN)	2017062849 (SN)	2017063018 (SN)
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2017062903 (SN)	2017062791 (SN)	2017062956 (SN)	2017062851 (SN)	2017063020 (SN)
2017062904 (SN)	2017062792 (SN)	2017062957 (SN)	2017062852 (SN)	2017063021 (SN)
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2017062906 (SN)	2017062794 (SN)	2017062959 (SN)	2017062854 (SN)	2017063023 (SN)
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2017062908 (SN)	2017062796 (SN)	2017062961 (SN)	2017062856 (SN)	2017063025 (SN)
2017062909 (SN)	2017062797 (SN)	2017062962 (SN)	2017062857 (SN)	2017063026 (SN)
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产品编号	产品编号	产品编号	产品编号	产品编号
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