

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） 何春霞
报告日期：2017.7.7

附页

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2020111910(SN)	2020112027(SN)	2020111526(SN)	2020112021(SN)	2020112131(SN)
2020111911(SN)	2020112028(SN)	2020111527(SN)	2020112022(SN)	2020112132(SN)
2020111912(SN)	2020112029(SN)	2020111528(SN)	2020112106(SN)	
2020111915(SN)	2020112030(SN)	2020111529(SN)	2020112109(SN)	
2020111922(SN)	2020112031(SN)	2020111530(SN)	2020112116(SN)	
2020111930(SN)	2020112032(SN)	2020111531(SN)	2020112118(SN)	
2020111931(SN)	2020112101(SN)	2020111532(SN)	2020112127(SN)	