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BC-FM-Q03-1

Rev. 1

医疗器械召回事件报告表

Medical Device Recall Reporting Form

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	
Submit to: Provincial Food and Drug Administration Department of Enterprise's Location					
Device Registration / Record Department					
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Device Registral	Device Registration / Record Department							
产品名称 Product Name	PTA 球囊扩张导管	注册证或备案凭证编码 Code of Registration or Record Certificate	国械注进 20183032612					
生产企业名称 Name of Manufacturer	Bard Peripheral Vascular, Inc.							
代理人名称	巴德医疗科技 (上海) 有限公司							
Name of Agent	Bard Healthcare Science (Shanghai) Co., Ltd							
召回单位负责人和联系方式,经办人								
和联系方式	刘博 +86 021 23254640;							
The Name and Contact Information of Responsible Person and Handler of the Recall Implementing Unit	赵晟 +86 021 23254169							
	推荐用于股动脉、髂动脉、和肾动脉的经皮腔内血管成形术治疗先天							
产品的适用范围 Application Scope of the Product	或后天动静脉透析瘘阻塞病变。还推荐本器械用于外周血管覆膜支架							
Approacion scope of the Froduct	的后扩张。该导管不适用于冠状动脉。							
涉及地区和国家 The Countries and Regions Involved	美国,台湾	召回级别 Level of Recall	III 三级					
涉及产品生产(或进口中国)批次、		涉及产品						
数量 The Batch Number and Quantity of Involved Domestic Product or Import	总进口数量: 0	型号、规格 The Model No. and Specification of	CQ7564					
Product		Involved Product						



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REDU2646 REDU2646 REDU2646 REDU2646 REDU2646 Sales Quantity of Involved Product In Chinese Market 召回原因简述 该产品的境外生产企业识别出,该批次的"PTA 球囊扩张导管"包装 Briefly Describe the Reason for Recall 纠正行动简述 该涉及批号产品并未进口至中国,该召回事件不影响中国市场,故在 (包括召回要求和处理方式等) Briefly Describe the Corrective Activity (Including Recall			涉及产品在中国的销		
Sales Quantity of Involved Product In Chinese Market 召回原因简述 这产品的境外生产企业识别出,该批次的"PTA 球囊扩张导管"包装 Briefly Describe the Reason for Recall 纠正行动简述 该涉及批号产品并未进口至中国,该召回事件不影响中国市场,故在 (包括召回要求和处理方式等) Briefly Describe the Corrective Activity (Including Recall		REDU2646	售数量	 	0
Involved Product In Chinese Market 召回原因简述			Sales Quantity of		
召回原因简述 该产品的境外生产企业识别出,该批次的"PTA 球囊扩张导管"包装 时使用了错误尺寸的球囊。	(e.g., Batch Number)		Involved Product In		
Briefly Describe the Reason for Recall 时使用了错误尺寸的球囊。 纠正行动简述 (包括召回要求和处理方式等) Briefly Describe the Corrective Activity (Including Recall			Chinese Market		
タロス と 対して	召回原因简述	 该产品的境外生产企业识别出,该批次的"PTA 球囊扩张导管"包 			包装
该涉及批号产品并未进口至中国,该召回事件不影响中国市场,故在 (包括召回要求和处理方式等) Briefly Describe the Corrective Activity (Including Recall	Briefly Describe the Reason for Recall	时使用了错误尺寸的球囊。			
(包括召回要求和处理方式等) Briefly Describe the Corrective Activity (Including Recall	纠正行动简述				
(包括召回要求和处理方式等) Briefly Describe the Corrective Activity (Including Recall		 该涉及批号产品并未讲口至中国,该召回事件不影响中国市场,故在			
Activity (Including Recall	(包括召回要求和处理方式等)			37 13 1 12 1 27	1ANG
and the same of th	Briefly Describe the Corrective	中国无需采取任何行动和处理措施。		小有	
Requirements, Dealing Methods, etc.)	Activity (Including Recall				

报告单位:

盖章/

Reporting Unit: (Affix with Stamp)

报告人: (签字) 刘博

Reporter: (Signature)

负责人: 赵晟

Responsible Person: (Signature)

报告日期: 2020年10月9日

Reporting Date: