المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication رسالة سلامة

Malfunction caused by intermittent incomplete mixing of epoxy during manufacture

Device/ Product Description:	Subset of Assurity and Endurity Pacemakers
Affected Lot Number:	Models: PM1152, PM1160, PM1172, PM1240, PM1272, PM2152, PM2160, PM2172, PM2240, PM2260, PM2272 Devices manufactured on specific manufacturing equipment between 2015 and 2018
Manufacturer:	St. Jude Medical Inc
Problem:	Malfunction caused by intermittent incomplete mixing of epoxy during manufacture, which may allow moisture ingress into the pulse generator header.
Recommendation /Actions:	Please see "Patient Management Recommendation" in the FSN. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999) unified call center

Devices/Products photo:		
Authorized Representative Details	AR name:	Al-Jeel Medical & Trading Co. LTD
	Assigned Contact Person:	Meshal Aleshaiwy
	Mobile/Phone:	+(966) 508827808
	Email:	Aljeel.sfda@aljeel.com