Class 2 Device Recall Plus 30 PRIORITY PACK (Accessories Kits)

Date Initiated by Firm: July 03, 2018
Create Date: February 27, 2019
Recall Status: Open, Classified
Recall Number: Z-0960-2019
Recall Event ID: 82015
510(K) Number: K962495
Product Classification: Syringe, balloon inflation, Product Code MAV
Product: PLUS 30 PRIORITY PACK Accessory Kit

Product Usage: Is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (e.g., balloon dilatation catheters, atherectomy devices, stent delivery systems, intravascular ultrasound devices).

Code Information: Device Identifier #: 08717648 01360 7 Part Number: 1000185 Lot number: 60047593
Recalling Firm/Manufacturer: Abbott Vascular
26351 Ynez Rd
Temecula CA 92591-4630
For Additional Information Contact: Customer Service 800-227-9902
Manufacturer Reason for Recall: Incorrect expiration being entered for one lot.
FDA Determined Cause: Incorrect or no expiration date

Action: Abbott Vascular sent an Urgent Field Safety Notice/Device Recall letter dated July 3, 2018 to affected customers. The letter identified the affected product, problem and actions to be taken. The letter instructed customers to: "Review inventory and stop using affected devices. " Complete and return the attached Effectiveness Check Form " Return the unused identified products to Abbott Vascular" Share this notification with other relevant personnel in their organization For questions contact Abbott Representative or Customer Service department on 800-227-9902.

Quantity in Commerce: 26 units
Distribution: US Nationwide Distribution - NC and NY

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=170566
04/03/2019