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

See Related Information[22]

Date Initiated by Firm	July 03, 2018
Create Date	February 27, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-0960-2019
Recall Event ID	82015[23]
510(K)Number	K962495[24]
Product Classification	Syringe, balloon inflation[25] - **Product Code** MAV[26]
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 26531 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 [2]	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