Class 2 Device Recall Stroke Fast Pack(TM)

See Related Information 22

Date Initiated by Firm	November 03, 2017
Date Posted	December 05, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0275-2018
Recall Event ID	78607[23]
510(K)Number	K132641[24] K143077[25] K113260[26] K113778[27] K151667[28]
Product Classification	Catheter, thrombus retriever[29] - **Product Code** NRY[30]
Product	Stroke Fast Pack(TM), Trevo(TM) XP, TREVO(TM) XP PROVUE RETRIEVER, 6 mm, 25 mm; Excelsior(TM) XT-27(tm), MICROCATHETER,150 cm, 6 cm; AXS Catalyst(TM) 6, Distal Access Catheter, 0.060 in, 132 cm, UPN M0033PK62523002 Stroke intervention kit
Code Information	Lot Numbers: QXC10200044, exp. date 28-Aug-18; QXC10200043, exp. date 28-Aug-18
Recalling Firm/ Manufacturer	Stryker Neurovascular 47900 Bayside Pkwy Fremont CA 94538-6515
For Additional Information Contact	Angela Beckman 510-413-2900
Manufacturer Reason for Recall	Stryker Neurovascular has become aware that some 3-Pack Stroke Fast Packs and Trevo Procedure Packs were manufactured using a carton sleeve where the sleeve label contents did not match the physical contents within the pack.
FDA Determined Cause [2]	Labeling Change Control
Action	The firm, Stryker Neurovascular, sent an "Urgent Medical Device Voluntary Recall Immediate Action Required" letter initiating their recall on 11/01/2017. The letter described the product, problem and actions to be taken. The consignees were instructed to immediately check internal inventory; remove and discard the procedure pack carton sleeve; circulate notice; maintain awareness of notice internally until all required actions have been completed with your facility; inform Stryker of any subject devices distributed to other organization, and complete and return customer response form to your nominated Stryker Representative or to NVFieldActions@stryker.com. If you have any questions, call 510-413-2593; email: geraldine.ahern@stryker.com or 510-413-2900.
Quantity in Commerce	2 units
Distribution	International Distribution to: Germany, Slovakia and Israel.
Total Product Life Cycle	TPLC Device Report[31]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA