Class 2 Device Recall Stroke Fast Pack(TM)

Date Initiated by Firm
November 03, 2017

Date Posted
December 05, 2017

Recall Status
Open, Classified

Recall Number
Z-0275-2018

Recall Event ID
7860723

510(K)Number
K13264124, K14307725, K11326026, K11377827, K15166728

Product Classification
Catheter, thrombus retriever - Product Code NRY29

Product
Stroke Fast Pack(TM), Trevo(TM) XP, TREVO(TM) XP PROVUE RETRIEVER, 6 mm, 25 mm; Excelsior(TM) XT-27(tm), MICROCATHERET, 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
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 Report31

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