FDA

Class 1 Device Recall Penumbra 3D Revascularization Device

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See Related Information[22]

Date Initiated by Firm	June 09, 2017
Date Posted	June 22, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2702-2017
Recall Event ID	77571[23]
510(K)Number	K162901[24]
Product Classification	Catheter, thrombus retriever[25] - **Product Code** NRY[26]
Product	Penumbra 3D Revascularization Device It is indicated for used in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral-M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Code Information	Lots C00644, C00645, C00646, C00717
Recalling Firm/ Manufacturer	Penumbra Inc. 1 Penumbra Alameda CA 94502-7610
For Additional Information Contact	Michaela Mahl 510-748-3288
Manufacturer Reason for Recall	Penumbra has identified an issue in these four lots involving a raw material component of the delivery wire. This issue could result in breakage of the delivery wire, which could potentially lead to serious patient injury or death.
FDA Determined Cause [2]	Component change control
Action	Penumbra sent an Urgent Voluntary Field Removal Notice dated June 9, 2017. Customers were instructed to inspect current inventory and remove any affected units for return. Customers were also instructed to return the response form. Penumbra has identified an issue in these four lots involving a raw material component of the delivery wire. This issue could result in breakage of the delivery wire, which could potentially lead to serious patient injury or death. Penumbra personnel will contact customers directly to arrange return of affected units and replacement of returned product at no charge to them. Customers with question should call 1-510-748-3288.
Quantity in Commerce	155 units
Distribution	Nationwide Distribution to the following states: AZ, CA, CO, FL, IN, MA, MI, MN, NV, NY, OH, OK, PA, SC, TN, TX, UT, VA, WV
Total Product Life Cycle	TPLC Device Report[27]