Class 1 Device Recall Penumbra 3D Revascularization Device

Date Initiated by Firm: June 09, 2017
Date Posted: June 22, 2017
Recall Status: Open, Classified
Recall Number: Z-2702-2017
Recall Event ID: 7757123
510(K) Number: K16280124

Product Classification: Catheter, thrombus retriever - Product Code NRY25
Product: Penumbra 3D Revascularization Device
It is indicated for use 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: 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 Report27

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=156554