FDA

See Related Information[22]

Class 2 Device Recall BioFlo PICC (NV) 5FDL55cm Maximal Barrier Nursing Kit

Date Initiated by Firm	May 10, 2018
Create Date	June 14, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-2223-2018
Recall Event ID	80169[23]
510(K)Number	K163452[24]
Product Classification	Catheter, intravascular, therapeutic, long-term greater than 30 days[25] - **Product Code** LJS[26]
Product	BioFlo PICC (NV) 5FDL-55cm Maximal Barrier Nursing Kit w/70cm Nitinol Wire PG, Catalog Number 75-033
Code Information	UPN: H965750335; Lot: 5310029, 5310762
Recalling Firm/ Manufacturer	Angiodynamics Inc. (Navilyst Medical Inc.) 10 Glens Falls Tech Park Glens Falls NY 12801-3864
For Additional Information Contact	David Greer 518-795-1676
Manufacturer Reason for Recall	A component of the kits might contain unsafe levels of bacterial endotoxins (pyrogens).
FDA Determined Cause [2]	Material/Component Contamination
Action	Urgent Medical Device Recall letters were sent to customers on 5/10/18. The letters instructed customers to do the following: IMMEDIATELY Stop using the product subject to recall. Remove any affected (recalled) product from your inventory (whether in labs, Central Supply, Shipping and Receiving or ANY other location). Segregate this product in a secure location for return to AngioDynamics, Inc. Forward a copy of this recall notification to all sites to which you have distributed affected product. Complete and return the Reply Verification Tracking Form. If affected product is located in your institution, please call AngioDynamics Customer Service at 1-800-772-6446 between 8:00 a.m. and 7:00 p.m. (Monday Friday: Eastern Standard Time) to obtain a replacement or credit for your returned product.
Quantity in Commerce	81 boxes
Distribution	The products were distributed to the following US states: AZ, CA, CO, CT, DC, FL, GA, IL, IN, KS, KY, LA, MD, MI, MN, MO, MS, MT, NC, ND, NJ, NM, NV, NY, OH, OK, OR, PA, SC, TN, TX, WA, WI, and WV. The products were distributed to the following foreign countries: Canada, China, Ireland, Spain.
Total Product Life Cycle	TPLC Device Report[27]

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