Class 2 Device Recall Gambro Cartridge Blood Set[6]

New Search Back to Search Results

Class 2 Recall
Gambro Cartridge Blood Set

See Related Information[21]

Date Posted	April 11, 2014
Recall Status[1]	Open
Recall Number	Z-1455-2014
Recall Event ID	67797[22]
Product Classification	Set, Tubing, Blood, With And Without Anti-Regurgitation Valve[23] - **Product Code** FJK[24]
Product	Gambro Cartridge Blood Set, blood transport system for hemodialysis, Model Number(s): 101025 (003410510) - Cartridge set, STND PRM LN and 103401 (003414500) - Cartridge set, PRM_LN_INJ_PT. The Gambro Cartridge Sets are single use sterile tubing sets intended to provide extracorporeal blood transport circuit for hemodialysis treatments for Gambro Phoenix and COBE Centrisystem 3 (and 3+) Dialysis Delivery Systems.
Code Information	Lot number: 1000039228, 1000048340, 1000050644, 1000050648, 1000054032, 1000058516, 1000064913, 1000065817, 1000065823, 1000066430, 1000063347, 1000067984, 1000068071, 1000071417, 1000071430, 1000073434, 1000073436, 1000073438, 1000074660, 1000074661, 1000074662, 1000075553
Recalling Firm/ Manufacturer	Gambro Renal Products, Incorporated 14143 Denver West Pkwy Lakewood, Colorado 80401-3266
Manufacturer Reason for Recall	Occluded heparin tubing events preventing anticoagulation dosing on the Gambro Cartridge Blood Sets.
FDA Determined Cause [2]	PRODUCTION CONTROLS: Process Control
Action	On 12/9/13 and 3/12/14, a field safety notice sent via UPS overnight delivery informing customers of issue and if any customer wants to return product, a hold at distribution centers and manufacturer quarantine areas. Upon reconciliation of returned product a destruction disposition with certification.
Quantity in Commerce	306,525 sets (20435 boxes of 15 sets)
Distribution	Worldwide Distribution-USA (nationwide) and the countries of Canada, Mexico, and Colombia.
Total Product Life Cycle	TPLC Device Report[25]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[26]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm