Class 2 Device Recall Gambro Cartridge Blood Set

Date Posted: April 11, 2014
Recall Status: Open
Recall Number: Z-1455-2014
Recall Event ID: 67797

Product Classification: Set, Tubing, Blood, With And Without Anti-Repurification Valve
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, 10000560644, 10000560648, 1000056032, 1000056516, 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: 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

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

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm