Class 2 Device Recall CytoGuard Closed Luer Connector

See Related Information [22]

Date Initiated by Firm	April 10, 2017
Create Date	May 23, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2155-2017
Recall Event ID	77112[23]
510(K)Number	K112636[24]
Product Classification	Set, administration, intravascular[25] - **Product Code** FPA[26]
Product	CytoGuard Closed Luer Connector, Intravenous access 2 cartons of 50 units each (100 units per case)
Code Information	Lot # , 1240156001, 1240156002, 1240156003, 1240156004, 1370249001, 1370251101, 1370257101, 1370259201, 1370268401, 1370270401, 1370273801, 1470311101, and 1570315301
Recalling Firm/ Manufacturer	B Braun Medical Inc 200 Boulder Dr Breinigsville PA 18031-1532
For Additional Information Contact	610-266-0500
Manufacturer Reason for Recall	B. Braun is voluntarily recalling 13 lots of CytoGuard Closed Luer Connector due to a potential for some blisters to be punctured resulting in a compromised sterility barrier.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	B. Braun mailed an Urgent Medical Device Recall Notice to affected customers to inform them of the issue. Customers were asked to determine their current inventory and to not destroy any of the product; however, product should be discontinued immediately and quarantined and return the acknowledgement form for product return.
Quantity in Commerce	417,600 units
Distribution	United States Nationwide distribution
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 identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = FPA and Original Applicant = B. BRAUN MEDICAL, INC.[29]