Class 2 Device Recall Dynarex CPR Shield With One Way Valve

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Class 2 Recall
Dynarex CPR Shield With One Way Valve

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Date Posted	July 25, 2014
Recall Status[1]	Open
Recall Number	Z-2117-2014
Recall Event ID	68681[22]
Premarket Notification 510(K) Number	K052743[23]
Product Classification	Valve, Non-Rebreathing[24] - **Product Code** CBP[25]
Product	CPR Shield With One Way Valve and Barrier Filter, Reorder No. 4921 --- Dynarex label, 100 per case --- Manufactured for: Dynarex Corporation, Orangeburg, NY 10962 - Made in China. Used as a physical barrier for mouth to mouth resuscitation.
Code Information	Lot Numbers 28619 & 28621
Recalling Firm/ Manufacturer	Dynarex Corporation 10 Glenshaw St Orangeburg, New York 10962-1207
Manufacturer Reason for Recall	"THIS SIDE UP" is on the wrong side of the product. This error poses a potential health hazard if the wrong labeling is followed by caregivers.
FDA Determined Cause [2]	TRAINING: Employee Error
Action	Voluntary Device Recall letters (dated 7/01/14) and recall verification forms were sent to customers via US Postal First Class Mail on 7/02/14. The letters instructed customers to check their inventory for the specific lots, discontinue distributing them, and quarantine them immediately. Customers were to promptly contact Dynarex Credit & Return Representative Avi Celnick at 1-845-365-8200 ext. 6644 to arrange for product return and obtain an RGA #. For questions, please call Dynarex's toll free number 1-888-396-2739.
Quantity in Commerce	Domestic: 208 cases; Foreign: 42 cases
Distribution	Worldwide Distribution -- USA, Canada, and Mexico.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = CBP and Original Applicant = DYNAREX CORP.[28]

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