Class 2 Recall Ameda

See Related Information[23]

Date Posted	March 26, 2015
Recall Status[1]	Open
Recall Number	Z-1326-2015
Recall Event ID	70599[24]
Premarket Notification 510(K) Number	K912355[25]
Product Classification	Pump, Breast, Non-Powered[26] - **Product Code** HGY[27]
Product	Ameda One-Hand Manual Breast Pump (SKU 17161) - Primary packaging is 6 pouches with Tyvek header (9.5 x 13.63 x 3.75") within a secondary corrugated shipper (16 x 11.02 x 5.12" inner dimensions). The device is indicated for assisted expression of milk using manual suction.
Code Information	SKU 17161; Lot 5A22
Recalling Firm/ Manufacturer	Ameda, Inc. 485 E Half Day Rd Ste 320 Buffalo Grove, Illinois 60089-8806
Manufacturer Reason for Recall	Devices were not sterilized
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	Ameda sent an URGENT: MEDICAL DEVICE RECALL letter dated February 12, 2015 to all affected customers. The letter included instructions for distributors to: 1) quarantine the recalled products; 2) complete and return the enclosed Recall Response Forms within 3 days of receiving the letter; 3) upon receipt of the completed Recall Response Form, an Ameda representative would contact the distributor to make arrangements for the return of the recalled products; 4) Ameda will use the information provided in the returned Recall Response Form to contact the distributor's customers of record to arrange for the return of recalled product that was already shipped to the customers of record; and, 5) replacement product will be shipped to both distributors and their customers of record upon receipt of the completed Recall Response Form. Questions about this recall will be answered by Ameda personnel who can be reached at 847-964-2645.
Quantity in Commerce	1763
Distribution	Nationwide Distribution including CA, FL, GA, IA, IL, IN, LA, MA, MD, MO, MS, NC, NJ, NY, OK, PA, RI, SC, TN, TX, UT, VA, and WA.
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[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 = HGY and Original Applicant = HOLLISTER, INC.[30]