Class 2 Recall Digital Temple Thermometer

See Related Information[22]

Date Posted	December 16, 2015
Recall Status[1]	Open
Recall Number	Z-0412-2016
Recall Event ID	72686[23]
Premarket Notification 510(K) Number	K103617[24]
Product Classification	Thermometer, Electronic, Clinical[25] - **Product Code** FLL[26]
Product	Digital Temple Thermometer labeled under: Bestmed, Good Neighbor (Amerisource Bergen), Kroger, Medline, Meijer, Premier Value, Safeway, Life Brand, Target, Top Care, Best Choice, Western Family. Device is packaged in plastic blister with cardboard insert, 2 AAA batteries installed, a Quick Start Guide, and an Instruction Manual booklet. Product Usage: Device is a handheld thermometer that employs a thermistor sensor intended for people to take a human body temperature at the temporal artery location, the area between the outer corner of the eye and the hairline directly over the temporal artery.
Code Information	Model KD-2201. all lots produced during the 36th week of year 2012 (09/03-07/2012) through and including the 37th week of year 2015 (09/07-13/2015). Lot No. S/N: 3612 through S/N: 3715"
Recalling Firm/ Manufacturer	Bestmed, LLC 331 Corporate Cirle Unit E Golden, Colorado 80401
For Additional Information Contact	Alex Burney 303-271-0300 Ext. 113
Manufacturer Reason for Recall	Bestmed is initiating a field action for Digital Temple Thermometer (DTT) Bestmed is initiating a field action for Digital Temple Thermometer (DTT) due to an incorrect calibration of the thermometer that causes the device to display inaccurate and frequently lower temperatures than the actual body temperature of the user.
FDA Determined Cause [2]	PRODUCTION CONTROLS: Process Control
Action	Consignees were notified verbally about 11/12/15. Written notification is planed and will include instructions on the identification of the Affected Device, potential health risk, method for return, and manner of restitution for the cost of the Affected Device.
Quantity in Commerce	305,548
Distribution	US Nationwide Distribution and the country of Canada.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.