Class 2 Device Recall BOND

See Related Information[22]

Date Initiated by Firm	July 30, 2021
Create Date	September 16, 2021
Recall Status[1]	Open[3], Classified
Recall Number	Z-2481-2021
Recall Event ID	88453[23]
Product Classification	Immunohistochemistry reagents and kits[24] - **Product Code** NJT[25]
Product	BOND Ready-To-Use Primary Antibody CDX2 (EP25), REF PA0375
Code Information	Product Code PA0375, Lot 69909
Recalling Firm/ Manufacturer	Leica Microsystems, Inc. 1700 Leider Ln Buffalo Grove IL 60089-6622
For Additional Information Contact	800-225-8867
Manufacturer Reason for Recall	Product may not perform as specified in IFU.
FDA Determined Cause [2]	Unknown/Undetermined by firm
Action	The firm notified their consignees by email on 07/30/2021. The notice explained the issue and requested destruction of the product.
Quantity in Commerce	237 units
Distribution	US Nationwide distribution.
Total Product Life Cycle	TPLC Device Report[26]

[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[27].

[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.

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=88453
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NJT
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NJT
26. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=NJT
27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm

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27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm