Class 2 Device Recall VACUETTE TUBE 2 ml 9NC Coagulation sodium citrate 13x75 mm blue capwhite ring, sandwich tube, non

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Date Initiated by Firm	August 20, 2021
Create Date	September 22, 2021
Recall Status[1]	Open[3], Classified
Recall Number	Z-2507-2021
Recall Event ID	88563[23]
510(K)Number	K971221[24]
Product Classification	Tubes, vacuum sample, with anticoagulant[25] - **Product Code** GIM[26]
Product	Greiner Bio-One VACUETTE¿ TUBE 2 ml 9NC Coagulation sodium citrate 3.2% 13x75 blue cap-white ring, sandwich tube, non-ridged
Code Information	Lot # B210533B Expiration 05/10/22 and B210439J Expiration 04/13/2022.
Recalling Firm/ Manufacturer	Greiner Bio-One North America, Inc. 4238 Capital Dr Monroe NC 28110-7681
For Additional Information Contact	Technical Service 800-515-8112
Manufacturer Reason for Recall	Complaint of tubes clotting due to variation of anticoagulant and/or tubes have low vacuum.
FDA Determined Cause [2]	Under Investigation by firm
Action	A letter was sent on August 20, 2021 with the following actions: Necessary actions: We need your assistance to address this recall. Please perform the following steps. " Stop using the above-mentioned product (concerned item/lot) immediately and isolate defective products in your facility. " Assess risks and consequences for the use of this defective product in

	accordance with your procedures and take appropriate action. " Complete the attached Product Disposition Site Confirmation form and fax to Greiner Bio-One North America, Inc. at 800.726.0052 or email to patech@gbo.com. This form is to confirm that you have discarded/destroyed all products from these items/lots. We will replace the product after the completed form is sent to Greiner. If you have additional questions, please call our Technical Service at 800-515-8112.
Quantity in Commerce	956,400
Distribution	US Nationwide distribution in the states of AL, AZ, CA, CT, FL, GA, IL, IN, KY, LA, MD, ME, MO, MT, NC, NE, NM, NV, NY, OH, OR, PA, TX, VA, WA and Puerto Rico.
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 = GIM and Original Applicant = GREINER AMERICA, INC.[29]

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4. http://www.fda.gov/MedicalDevices/default.htm
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14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
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=88563
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K971221
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GIM
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GIM
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=GIM
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=GIM&knumber=&applicant=GREINER%20AMERICA%2C%20INC%2E

6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
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18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
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=88563
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K971221
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GIM
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GIM
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=GIM
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=GIM&knumber=&applicant=GREINER%20AMERICA%2C%20INC%2E