Class 2 Device Recall CERTAIN(R) BELLATEK(R) TIN ABUTMENT 3.4MM

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See Related Information[22]

Date Initiated by Firm	February 26, 2019
Create Date	August 02, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-2140-2019
Recall Event ID	82263[23]
510(K)Number	K052648[24] K102209[25]
Product Classification	Abutment, implant, dental, endosseous[26] - **Product Code** NHA[27]
Product	CERTAIN(R) BELLATEK(R) TIN ABUTMENT 3.4MM, Item Number IEDAN3 - Product Usage: BIOMET3i Restorative products are intended for use as an accessory to endosseous dental implants for placement in the maxilla and mandible
Code Information	Lot Numbers/UDI: 8442784-1/(01)00844868031130(10)8442784-1, 8442469-1/(01)00844868031130(10)8442469-1, 8442689-1/(01)00844868031130(10)8442689-1
Recalling Firm/ Manufacturer	Biomet 3i, LLC 4555 Riverside Dr Palm Beach Gardens FL 33410-4200
For Additional Information Contact	Zimmer Biomet, Customer Service 888-800-8045
Manufacturer Reason for Recall	During manufacturing, the screw stop ledge was not made to specification and location within the abutment, resulting in the screw head seating deeper in the abutment with no positive stop.

FDA Determined Cause [2]	Process control
Action	The firm disseminated the notices by email on 02/26/2019. The letter requested that the dental laboratories quarantine and return any unused product and to further notify the affected clinician referral.
Quantity in Commerce	3 units
Distribution	Nationwide and Puerto Rico, Canada, and Australia
Total Product Life Cycle	TPLC Device Report[28]

[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[29].

[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 = NHA and Original Applicant = BIOMET 3I, INC.[30] 510(K)s with Product Code = NHA and Original Applicant = IMPLANT INNOVATIONS, INC.[31]

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10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm

11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
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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=82263
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K052648
25. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K102209
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NHA
27. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NHA
28. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=NHA
29. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
30. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=NHA&knumber=&applicant=BIOMET%203I%2C%20INC%2E
31. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=NHA&knumber=&applicant=IMPLANT%20INNOVATIONS%2C%20INC%2E

Page Last Updated: 08/06/2019

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8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
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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=82263
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K052648
25. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K102209
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NHA
27. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NHA
28. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=NHA
29. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
30. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=NHA&knumber=&applicant=BIOMET%203I%2C%20INC%2E
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