Class 2 Device Recall Compress; Mini Compress

Date Initiated by Firm	August 21, 2019
Create Date	November 22, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-0519-2020
Recall Event ID	83783[23]
510(K)Number	K062998[24] K112905[25]
Product Classification	Prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented[26] - **Product Code** KWY[27]
Product	Compress, Mini Compress; Item Nos. 178350 178351 178352 178353 178354 178355 178356 178357 178358 178359 178360 178361 178362 178363 178364 178365 178366 178367 178368 178369 178370 178371 178372 178373 178464 178472 178480 178488 178496 178504 178575 178576 178577 178578 178579 178580 178730 178731 178732 178733 178734 178735 178354S 178754

	178755 178756 178757 178758 178759
	Product Usage: 1) Correction of revision of unsuccessful osteotomy, arthrodesis or previous joint replacement 2) Tumor resections 3) Revision of previously
Code Information	All lots manufactured between January 2008 - May 2019: 043240 073900 150190 236460 313350 391940 454660 460760 482880 498540 512280 544320 545330 633210 670360 762790 792260 792270 81759(
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 56 E Bell Dr Warsaw IN 46582-6989
For Additional Information Contact	411 Technical Services 574-371-3071
Manufacturer Reason for Recall	Elevated levels of bacterial endotoxin and residual debris remain on the devices due to cleaning issue.
FDA Determined Cause [2]	Environmental control
Action	On September 11, 2019, the firm began notifying distributors and customers of the recall via an Urgent Medical Device Recall letter. The letter informed cons Customers were asked to assist their Zimmer Biomet sales representative and quarantine all identified product. The sales representative will remove the pro If you have further questions or concerns, please call customer service at 574-371-3071 between 8:00 am and 5:00 pm ET, Monday through Friday. Calls re There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow-up schedule.
Quantity in Commerce	219988 units
Distribution	US Nationwide distribution and countries of Argentina, Australia, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Italy, Netherlands, Indi
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

[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 = KWY and Original Applicant = BIOMET MANUFACTURING CORP.[30] 510(K)s with Product Code = KWY and Original Applicant = BIOMET ORTHOPEDICS LLC.[31]

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28. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=KWY
29. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
30. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=KWY&knumber=&applicant=BIOMET%20MANUFACTURING%20CORP%2E
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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=83783
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