### Class 2 Device Recall; Mini Compress

<table>
<thead>
<tr>
<th>Date Initiated by Firm</th>
<th>August 21, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create Date</td>
<td>November 22, 2019</td>
</tr>
<tr>
<td>Recall Status</td>
<td>Open, Classified</td>
</tr>
<tr>
<td>Recall Number</td>
<td>Z-0519-2020</td>
</tr>
<tr>
<td>Recall Event ID</td>
<td>83783</td>
</tr>
<tr>
<td>510(K)Number</td>
<td>K062998, K112908</td>
</tr>
<tr>
<td>Product Classification</td>
<td>Prosthesis, hip, femoral, metal/polymer, cemented or uncemented</td>
</tr>
<tr>
<td>Product</td>
<td>Compress, Mini Compress; Item Nos. 178350</td>
</tr>
<tr>
<td></td>
<td>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, 178736, 178737, 178754</td>
</tr>
</tbody>
</table>
12/24/2019

Class 2 Device Recall Compress; Mini Compress

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 545330 63210 762790 792260 792270 81759C 178755 178756 178757 178758 178759

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 con-

Customers were asked to assist their Zimmer Biomet sales representative and quarantine all identified product. The sales representative will remove the prc

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

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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. 20

510(K)s with Product Code = KWY and Original Applicant = BIOMET ORTHOPEDICS LLC. 31

Links on this page:

3. https://www.fda.gov/
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmm/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/r1.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
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23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83783
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K062998
25. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K112905
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=KRY
27. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=KRY
28. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=KRY
29. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
30. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?
   start_search=1&productcode=KRY&knumber=&applicant=BIOMET%20MANUFACTURING%20CORP%2E
31. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=KRY&knumber=&applicant=BIOMET%20ORTHOPEDICS%20LLC%2E