MARKING BOOK INVOICE Promote and Reservoir 1714 and 1

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Biomet Integral Centralizer Hip System

6 510(k) | DeNovo8 | Registration & | Adverse | Recalls 11 | PMA 12 | HDE 13 | Classification 14 | Standards 15

Listing⁹ Events¹⁰ CFR Title 21¹⁶[Radiation-Emitting Products¹⁷[X-Ray Assembler¹⁸]Medsun Reports¹⁹[CLIA²⁰]TPLC²¹

New Search

Class 2 Device Recall Biomet Integral Centralizer Hip System

See Related Information

Back to Search Results

Date Posted

January 13, 2016

Recall Status¹

Open

Recall Number

Z-0650-2016

Recall Event ID

7252123

510(K)Number

K942479²⁴

Product Classification

Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous,

uncemented²⁵ - Product Code LZO²⁶

Product

Biomet Integral Centralizer Hip System, Lateralized Femoral Stem (Co-Cr-Mo),

9mm, 11mm, 13mm, 15mm, and 17mm

Code Information

Part #11-162709

9mm

Lots: 329750, 404380, 487400, 767120, 951680

Part # 11-162711

Lots: 329760, 505030, 505050

Part # 11-162713

13mm

Lots: 837750, 977460 Part # 11-162715

15mm

772410, 837780, 897070, 951810

Part # 11-162717

17mm

Lots: 311410, 410500, 535530, 712800, 728080, 829580

Recalling Firm/ Manufacturer

Biomet, Inc. 56 E Bell Dr

Warsaw IN 46582-6989

For Additional Information Contact Audrey Daenzer 574-372-1570

Manufacturer Reason

for Recall

PMMA is listed as a material on the label but the product does not contain PMMA.

FDA Determined

Cause 2

Labeling Change Control

Action

On 11/17/2015, URGENT MEDICAL DEVICE RECALL NOTICE notifications were sent to the affected distributors via courier with instructions for identifying and returning the affected product. The recall notification included a description of the reason for the recall, affected