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**Class 2 Device Recall Stryker Orthopaedics**

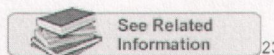


6 510(K) | DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup> | PMA<sup>12</sup> | HDE<sup>13</sup> | Classification<sup>14</sup> | Standards<sup>15</sup>  
 7 CFR Title | Radiation-Emitting Products<sup>17</sup> | X-Ray Assembler<sup>18</sup> | Medsun Reports<sup>19</sup> | CLIA<sup>20</sup> | TPLC<sup>21</sup> | Inspections<sup>22</sup>  
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**Class 2 Recall  
Stryker Orthopaedics**



<b>Date Posted</b>	May 19, 2015
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1633-2015
<b>Recall Event ID</b>	70994 <sup>24</sup>
<b>Premarket Notification 510(K) Number</b>	<u>K102019</u> <sup>25</sup>
<b>Product Classification</b>	<u>Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented</u> <sup>26</sup> - <b>Product Code LPH</b> <sup>27</sup>
<b>Product</b>	Stryker Howmedica Osteonics RESTORATION Acetabular Augment System; Howmedica Osteonics Corp., A subsidiary of Stryker Corporation Made in USA Sterile. Hip prosthesis component. The RESTORATION Acetabular Wedge Augments provide multiple options to address the wide range of bone deficiencies encountered in acetabular revision. The augments provide support for the shell in the acetabulum with superior and/or posterior defects.
<b>Code Information</b>	Ref #: Lot Number - 5096-4615:MMR8M8; 5096-4615:MMRLYD; 5096-4615:MNAYT7; 5096-5015:MMPO6K; 5096-5015:MMRWOJ; 5096-5015:MNADVA; 5096-5815:MNA40L; 5096-5820:MMR6HX; 5096-5825:MMRLD7; 5096-6225:MMPWO5; 5096-6225:MMRM2Y; 5096-6625:MMNM07
<b>Recalling Firm/ Manufacturer</b>	Stryker Howmedica Osteonics Corp. 325 Corporate Dr Mahwah, New Jersey 07430-2006
<b>For Additional Information Contact</b>	Mr. Paul Jahnke 201-831-5826
<b>Manufacturer Reason for Recall</b>	Stryker Orthopaedics initiated a voluntary product recall for specific lots of Triathlon Femoral, Scorpio Femoral, Restoration Wedge Augments distributed from their Mahwah Manufacturing Facility. It was found that the peel strength of the inner blister may have been below internal validated requirements. The strength of the seal is directly related to long term shelf life of the sterile barrier.
<b>FDA Determined Cause<sup>2</sup></b>	OTHER/UNDETERMINED: Under Investigation by the firm
<b>Action</b>	The firm, Stryker Orthopaedics, notified their Branches/Agencies via email on 8/15/2014 and sent an "Urgent Product Recall" letter dated 8/15/2014 with a Product Recall Acknowledgement Forms to their Branches/Agencies and consignees. The letter describes the product, issue, potential hazards and actions to be taken. The consignees were instructed to complete and return the attached Product Recall Acknowledgment Form within 5 days via fax to 855-251-3635; and return the affected product to the attention of Regulatory Compliance, Stryker Orthopaedics, 325 Corporate Drive, Mahwah NJ 07430. If you have any questions, feel free to contact Sr. Regulatory Compliance Specialist to 201-831-5826.
<b>Quantity in Commerce</b>	1,147 in total
<b>Distribution</b>	Worldwide Distribution: US (nationwide) including PR and countries of: Australia, Canada,