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Class 2 Device Recall Stryker Orthopaedics

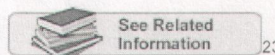


6 510(k) DeNovo⁸ | Registration & Listing⁹ | Adverse Events¹⁰ | Recalls¹¹ | PMA¹² | HDE¹³ | Classification¹⁴ | Standards¹⁵
 CFR Title | Radiation-Emitting Products¹⁷ | X-Ray Assembler¹⁸ | Medsun Reports¹⁹ | CLIA²⁰ | TPLC²¹ | Inspections²²
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**Class 2 Recall
Stryker Orthopaedics**



Date Posted	May 19, 2015
Recall Status¹	Open
Recall Number	Z-1634-2015
Recall Event ID	70994 ²⁴
Premarket Notification 510(K) Numbers	K030978²⁵ K042343²⁶ K962152²⁷ K974556²⁸
Product Classification	<u>Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer²⁹ - Product Code JWH³⁰</u>
Product	Stryker Orthopaedics Scorpio Howmedica Osteonics Corp., A subsidiary of Stryker Corporation Made in USA Sterile. For use in total reconstructive replacement of the knee joint.
Code Information	Item number 26-3005L Lot numbers MNH0ND, MNH3V7, MNH8XR, MNHN0E, MNH6Y5; 70-3003L Lot MNE6NM; 70-3003R Lot MNE963; 70-3007L Lots MNE58K, MNE6HL, MNE8MN, MNEKXP; 70-3007R Lots MNEV2Y, MNEVDV, MNEN3D, MNEX43; 70-3013L Lot MMMXTY; 70-4104L Lots MNE0Y8, MNE2J2, MND743, MNDVDT; 71-3009L Lots MNE12D, MNEALW, MNEEE4, MNEXLK, MNEXV0; 71-3009R Lots MNELHM, MNEYNE; 71-3013L Lot MMR24J; 71-4104L Lot MMAKXS; 71-4503R Lots MMT7P8, MMT8J3, MNDKJ7; 71-4504L Lots MNE5D4, MNEHV1; 71-4504R Lots MND272, MNDD9D, MNEL8W; 71-4505L Lots MMT4KY, MMTPHS, MNAJ78, MNAN2L, MNDP2N; 71-4505R Lots MMTEW1, MNA062, MNANVA; 71-4506L Lots MNAJ1W, MNARAR, MNEL1Y, MNEW53; 71-4507L Lots MMT971, MMT9R5X1, MMTJRT, MNALJA, MND1V8; 71-4507R Lots MNA17E, MND4WP, MNEAAD, MNEM55; 71-4509R Lots MMR2HL, MND9AE; 80-4403L Lots MNE0LE, MNEJ70, MNEK3L; 80-4404R Lot MNHTRK, 80-4405L Lot MNERD1; 80-4405R Lots MNEEND, MNEHNO, MNEK42, MNEMNR, MNEMXH, MNEY4A; 80-4406L Lots MNA4HR, MNEH40, MNE37L, MNE769, MNE9RD, MNEATP, MNEX06, MNEXA8; 80-4407R Lots MNELAL, MNEP9K, MNEPVE; 80-4408L Lot MNEX9T; 80-4409L Lots MNE7H9, MNEDWK, MNEDXN; 80-4409R Lots MNE0R2, MNETXP, MNEVTV; 80-4411L Lots MNEN81, MNEWN4; 80-6404R Lot MNDKD0; 80-6405R Lots MMTA8L, MNA175; 80-6407L Lot MMRV9D; 80-6411L Lot MMP7TS; 81-4404R Lots MNE34H, MNE9WN, MNEKY7; 81-4405L Lots MNE3XK, MNE4OR, MNE473, MNE50T, MNE6A5, MNE7NN, MNE9DD, MNEDX6, MNEJ0N, MNELK5, MNERR2; 81-4405R Lots MNE5PE, MNE5W5, MNEA1T, MNEH09, MNEK9M, MNEP17, MNEPET, MNEPX6, MNER3V, MNEWW7, MNEXDP, MNEXLL, MNEY3R; 81-4406L Lots MNE0J3, MNE5D6, MNEA42, MNEHL1, MNEM0H, MNEMD4, MNEMJ8, MNEMPD, MNENAR, MNENP6, MNEW72; 81-4406R Lots MNE1XK, MNE5D2, MNEA75, MNED3A, MNEVLY, MNEYHH; 81-4407L Lots MNE127, MNE26L, MNE3KJ, MNE63T, MNE6XK, MNE71T, MNE8PT, MNE996, MNEPY7; 81-4407R Lots MMPE33, MNEOJ9, MNE217, MNE2NH, MNE3MH, MNE525, MNE5YP, MNE6WT, MNE7V2, MNE9J1, MNEA62, MNEAR2, MNEAXJ, MNED83, MNENNE, MNELEP, MNENM4, MNENY7, MNEPEP, MNERAV, MNETYX, MNEVN7, MNEW3Y, MNEW56, MNEWN0, MNEX5E, MNEXV1, MNEXVT, MNEY27, MNEYR6, MNHTW5; 81-4408L Lots MNE2VE, MNEAMY, MNEEM0, MNEYRT, MNEYK; 81-4408R Lots MNEO89, MNE2A1, MNE4DK, MNE7XV, MNE8N4, MNE9M9, MNEA4T, MNEAJ8, MNEMLA, MNET9J; 81-4409L Lots MNE4W5, MNE93H, MNEEEN, MNEVOY, MNEY57, MNEY74, MNE159, MNE1H2, MNE2DK, MNEM2D, MNENLJ, MNER77, MNEV0J; 81-4411R Lot MMTVXW; 81-4413L Lot MMP0MP; 81-6404R Lot MMTR58; 81-6407L Lot MMTDN7.
Recalling Firm/	Stryker Howmedica Osteonics Corp.