Class 2 Recall Stryker Orthopaedics See Related Information[23]

Date Posted	May 19, 2015
Recall Status[1]	Open
Recall Number	Z-1634-2015
Recall Event ID	70994[24]
Premarket Notification 510(K) Numbers	K030978[25] K042343[26] K962152[27] K974556[28]
Product Classification	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer[29] - **Product Code** JWH[30]
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, MNEPN6, MNEW72; 81-4406R Lots MNE1XK, MNE5D2, MNEA75, MNED3A, MNEVLY, MNEYHH; 81-4407L Lots MNE127, MNE26L, MNE3KJ, MNE63T, MNE6XK, MNE71T, MNE8PT, MNE996, MNEPYY; 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, MNEYYK; 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.

Manufacturer	325 Corporate Dr Mahwah, New Jersey 07430-2006
For Additional Information Contact	Mr. Paul Jahnke 201-831-5826
Manufacturer Reason for Recall	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.
FDA Determined Cause [2]	OTHER/UNDETERMINED: Under Investigation by the firm
Action	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.
Quantity in Commerce	1,147 in total
Distribution	Worldwide Distribution: US (nationwide) including PR and countries of: Australia, Canada, China, Brasil, France, Hong Kong, India, Italy, Mexico, Netherlands, Singapore, South Africa, Sweden, and Spain.
Total Product Life Cycle	TPLC Device Report[31]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[32]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database	510(K)s with Product Code = JWH and Original Applicant = HOWMEDICA OSTEONICS CORP[33] 510(K)s with Product Code = JWH and Original Applicant = HOWMEDICA OSTEONICS CORP.[34] 510(K)s with Product Code = JWH and Original Applicant = OSTEONICS CORP.[35]

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Class 2 Recall Stryker Orthopaedics See Related Information[23]

Date Posted	May 19, 2015
Recall Status[1]	Open
Recall Number	Z-1635-2015
Recall Event ID	70994[24]
Premarket Notification 510(K) Numbers	K042993[25] K070095[26]
Product Classification	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer[27] - **Product Code** JWH[28]
Product	Stryker Orthopaedics Triathlon 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 Lot number 5512-F-201 Lots JYET, KFVZ, KGLX ; 5512-F-202 Lots IPPOP, JYKX, KHZL, KJDN, KJHI, KJKY; 5512-F-301 Lots JTJA, KKAE, KKNB; 5512-F-302 Lots JXXF, KEYD, KFBY, KFTZ, KFXT, KHAB; 5512-F-401 Lots JWGY, KIED; 5512-F-402 Lots IUAJ, JJHT, JOMB, JWPF, JXXM, KGPE, KJMO, KLUP; 5512-F-501 Lots JXMV, KGKP; 5512-F-502 Lots KHWY, KJBK; 5512-F-601 Lots JIML, JIRX, KFAS, KIIY; 5512-F-602 Lots KEXE, KFOS, KFPI, KJAG, KKJW; 5512-F-701 Lot JKTF; 5512-F-801 Lots JWNL, JWPY; 5515-F-301 Lots IVXZD, JEPOD, JHZRA, JITNA, JITND,JJAFD, JJNYA, JJNYD, JKEND, JSNRD, JXBXA, JYFTD, JYGID, JYMTD,JYPJD, KFWHA, KFXID, KGAXD, KGJTD, KGXNA, KIBTA, KIEBA, KIGRD, KIYUD, KJABD, KJISD, KJRID; 5515-F-302 Lots IOLSD, IOLTD, IPRVD, IPTFD, IVGVA, IVLVD, JGIXD, JIGSD, JIYVD, JJSYA, JJWNA, JNVTA, JOWJD, JPFDA, JPHRA, JPIWA, JSZGD, JVYDD, JWPRA, JXBKD, JXOBA, JXXZD, JYBRA, JYBRD, JYKFD, JYKTA, JYMXA, JYNIA, JYNID, JYUED, JZDWD, JZEHD, JZFDD, KFNEA, KFOBA, KFOBD, KFOHD, KFVND, KGMFA, KGMFD, KGWGA, KGZFA, KHBGA, KIEXD, KJBFD, KJDLD, KJFXA, KJFXD, KJNPA, KKJOD; 5515-F-401 Lots JPDRA, JPIXD, JVLND, JVMTD, JXUDD, JYIDD, JYMUD, JZDSA, KABYA, KFDKD, KFMLA, KFPNA, KGAVD, KHEAA, KHKSA, KHZHA, KIATA, KIBVD, KIFMD, KIFOA, KIIFA, KJKBD, KKFYD; 5515-F-402 Lots JIFRD, JIGXD, JIMUD, JIRZD, JKESD, JLVSA, JLWTA, JOUGD, JPFEA, JPGKD, JYEIA, KAJID, KFSND, KGFLD, KGRBA, KGSHD, KGYOD, KJXDD, KKVHA, KLBHD, KLLBD; 5515-F-501 Lots HWHLA, IEXUA, IFDEA, IKEMD, JIAID, JILXA, JJBFD, JJTVD, JKGXD, JOXUA, JPMVD, JZRRA, KFSRA, KGIVD, KGKZA, KGSID, KGVHD, KGVPD, KHGPA, KHKAD, KHWRD, KHXWA, KJGBA, KKHFA, KKHFD, KLOSA; 5515-F-502 Lots IKRKA, JIDLA, JIEZD, JIVTA,JIYYD, JJWSA, JKAAD, JNVJA, JOPDD, JPFBD, JVUAD, JXBYD, JXFLA, JXTRD, JXYSA, JZHAD, JZKTD, KFNGD, KGTLA, KGTMA, KGYFA, KHGVA, KHGVA, KHGVD, KHOFD, KHPLA, KHRTA, KHWMA, KHWVA, KIDPA, KIJDA, KJGLD, KKMDD, KKOOD, KKPKA, KKWAA, KLBZA, KLMBA, KLSFA, KLSFD; 5515-F-601 Lots IPFTA, JIUMD, JJHZA, JMBTA, JWFHD, JWKTA, JXWXA, KABRD, KAGLA, KFISA, KFJXA, KGBVA, KGTDA, KHFSA, KHGNA, KHJAA, KHLIA, KHSWA, KHUAA, KHYED, KHZYA, KIGND, KJKOA; 5515-F-602 Lots JIYHD, JIZOA, JJBWD, JJWPD, JKDPD, JKERA, JPPKD, JJPSXD, JRBRA, JYTBD, KEZND, KFKDA, KFTMD, KFURA, KGIRA, KGNPD, KGRYD, KHJTD, KHPZA, KKXKA, KLKSA.
Recalling Firm/ Manufacturer	Stryker Howmedica Osteonics Corp. 325 Corporate Dr Mahwah, New Jersey 07430-2006
For Additional	Mr. Paul Jahnke