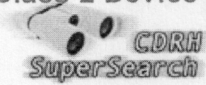


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Class 2 Device Recall Integra Cadence Total Ankle System

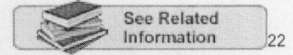


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Class 2 Device Recall Integra Cadence Total Ankle System



Date Initiated by Firm	January 20, 2017
Create Date	February 11, 2017
Recall Status ¹	Open ³ , Classified
Recall Number	Z-1192-2017
Recall Event ID	<u>76290</u> ²³
510(K)Number	<u>K151459</u> ²⁴
Product Classification	<u>Prosthesis, ankle, semi-constrained, cemented, metal/polymer</u> ²⁵ - Product Code HSN ²⁶
Product	Integra Cadence Total Ankle System
Code Information	Model Number, Item Description, and Lot Number: 10207101, Cadence Tibial Tray, Size 1, Right Lots: QJ0231, QJ0231-G, QJ0467, QJ0467-G; 10207102 Cadence Tibial Tray, Size 2, Right Lots: QJ0227, QJ0227-G, QJ0233, QJ0469, QJ0500, QJ0500-G; 10207103 Cadence Tibial Tray, Size 3, Right Lots: QJ0235, QJ0235-1, QJ0235-1-G, QJ0471, QJ0502-G; 10207104 Cadence Tibial Tray, Size 4, Right Lots: QJ0237, QJ02371, QJ0237-1G, QJ0237-G, QJ0473, QJ0504-G; 10207105 Cadence Tibial Tray, Size 5, Right Lots: QJ0239, QJ0239-1-G, QJ0239G, QJ0475; 10207111 Cadence Tibial Tray, Size 1X, Right Lots: QJ0232, QJ0232-G, QJ0468, QJ0499-G; 10207112 Cadence Tibial Tray, Size 2X, Right Lots: QJ0228, QJ0228-G, QJ0234, QJ0234-G, QJ0470, QJ0501-G; 10207113 Cadence Tibial Tray, Size 3X, Right Lots: QJ0236, QJ0236-1, QJ0236-1-1G, QJ0236-1G, QJ0472, QJ0503, QJ0503-G; , 10207114 Cadence Tibial Tray, Size 4X, Right Lots: QJ0238, QJ0238G, QJ0474, QJ0505-G; 10207201 Cadence Tibial Tray, Size 1, Left Lots: QJ0240, QJ0240G, QJ0249, QJ0476; 10207202 Cadence Tibial Tray, Size 2, Left Lots: QJ0242, QJ0242-1-G, QJ0242-2-G, QJ0242-G, QJ0478, QJ0478-G, QJ0507-G; , 10207203 Cadence Tibial Tray, Size 3, Left Lots: QJ0244, QJ0244G, QJ0253, QJ0480, QJ0480-G, QJ0509-G; 10207204 Cadence Tibial Tray, Size 4, Left Lots: QJ0246, QJ0246G, QJ0255, QJ0482; 10207205 Cadence Tibial Tray, Size 5, Left Lots: QJ0248, QJ0248G, QJ0257, QJ0484; 10207211 Cadence Tibial Tray, Size 1X, Left Lots: QJ0241, QJ0241G, QJ0477, QJ0477-G, QJ0506; , 10207212 Cadence Tibial Tray, Size 2X, Left Lots: QJ0243, QJ0243G, QJ0252, QJ0479, QJ0479-G, QJ0508, QJ0508-G; 10207213 Cadence Tibial Tray, Size 3X, Left Lots: QJ0245, QJ0245G, QJ0481, QJ0481-G, QJ0510, QJ0510-G; 10207214 Cadence Tibial Tray, Size 4X, Left Lots: QJ0247, QJ0247-G, QJ0256, QJ0483, QJ0483-G, QJ0511, QJ0511-G.
Recalling Firm/Manufacturer	Integra LifeSciences Corp. 311 Enterprise Dr Plainsboro NJ 08536-3344
For Additional Information Contact	609-275-0500
Manufacturer Reason for Recall	Posterior tibial fractures have been reported.
FDA Determined Cause ²	Use error