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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: Open, Classified
Recall Number: Z-1192-2017
Recall Event ID: 76290
510(K) Number: K151459
Product Classification: Prosthesis, ankle, semi-constrained, cemented, metal/polymer - Product Code HSN

Recalling Firm/Manufacturer: Integra LifeSciences Corp.
For Additional Information Contact: 311 Enterprise Dr Plainsboro NJ 08536-3344
Manufacter Reason for Recall: Posterior tibial fractures have been reported.
FDA Determined Cause: Use error