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Class 2 Device Recall Mac Pin NonCannulated Screw

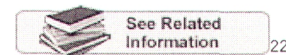


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Class 2 Device Recall Mac Pin NonCannulated Screw



Date Initiated by Firm	July 07, 2017
Create Date	January 10, 2018
Recall Status ¹	Open ³ , Classified
Recall Number	Z-0325-2018
Recall Event ID	77991 ²³
510(K)Number	K153152 ²⁴
Product Classification	Thoracolumbosacral pedicle screw system ²⁵ - Product Code NKB ²⁶
Product	Mac Pin Non-Cannulated Screw, 6.5 x 60mm
Code Information	Model #85-6560-1, Lot #132117
Recalling Firm/ Manufacturer	Amendia, Inc 1755 W Oak Pkwy Marietta GA 30062-2260
For Additional Information Contact	770-575-5224
Manufacturer Reason for Recall	Incorrect labeling for the lot of MAC Pins. Although the pins are laser as 460 mm in length, the pins are 60 mm in length.
FDA Determined Cause ²	Process control
Action	Customers were sent recall notification letters on 07/07/2017. Instructions included to examine inventory and quarantine affected products, notify customers if affected products were further distributed, coordinate the return of affected products back to Amendia, and to complete and return the questionnaire. If there are questions, Amendia Customer Service can be contacted at 770-575-5224.
Quantity in Commerce	41 screws
Distribution	Distribution to Georgia, USA.
Total Product Life Cycle	TPLC Device Report ²⁷

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated.

Learn more about [medical device recalls](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database [510\(K\)s with Product Code = NKB and Original Applicant = AMENDIA, INC.](#)²⁹