FDA

Class 2 Device Recall Phoenix Nail System

See Related Information[22]

Date Initiated by Firm	March 12, 2018
Create Date	March 27, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-1236-2018
Recall Event ID	79487[23]
510(K) Number	K091976[24]
Product Classification	*Rod, fixation, intramedullary and accessories*[25] - *Product Code HSB*[26]
Product	Phoenix Nail System, 3.5mm Inserter Connector, Short; Model Numbers: 14-441045, 14-440065S (kit) Accessory devices intended for use with an intramedullary nail system for alignment, stabilization and fixation of fractures.
Code Information	101450, 101480, 111700, 111760, 116820, 118330, 142400, 149540, 164240, 190740, 201170, 210470, 268070, 276080, 280600, 280610, 302860, 306510, 306520, 327060, 327070, 327310, 327450, 334390, 335080, 335090, 335400, 335860, 336050, 336590, 337680, 350280, 395470, 468260, 491750, 496810, 510290, 512200, 527380, 527390, 527400, 527410, 527420, 527430, 531370, 537580, 537690, 540340, 557600, 561800, 573000, 573010, 573020, 578820, 579370, 609980, 663130, 665910, 671300, 677620, 700420, 783690, 804170, 809490, 812420, 812480, 812490, 834860, 916980, 983220, 996210, 013740, 031700, 035820, 053600, 079000, 084440
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 56 E Bell Dr Warsaw IN 46582-6989
For Additional Information Contact	411 Technical Services 574-371-3071
Manufacturer Reason for Recall	Certain lots of the Phoenix Tibia Nail 3.5mm Inserter Instruments are being recalled due to reports of fracturing and remaining in the device implant.
FDA Determined Cause [2]	Device Design
Action	The firm, Zimmer Biomet, sent an "URGENT MEDICAL DEVICE RECALL (REMOVAL)" notice dated 3/12/2018 to its customers. The notice describes the product, problem and actions to be taken. The customers were instructed to the following: Risk Manager: 1. Review this notification and ensure affected personnel are aware of the contents. 2. Assist *Zimmer Biomet sales representative and quarantine affected product.* 3. *Zimmer Biomet* sales representative will remove the affected product from the facility. 4. Complete Certificate of Acknowledgement. a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com. Distributors: 1. Review this notification and ensure that affected team members are aware of the contents. 2. Locate and quarantine *affected product in your inventory.* 3. *Complete Inventory Return Certification Form and send* to CorporateQuality.PostMarket@zimmerbiomet.com within three (3) days. 4. Immediately return all affected product from your distributorship and from affected hospitals within your