Class 2 Device Recall The UNICP bone fixation system

Date Initiated by Firm: May 22, 2018
Create Date: July 16, 2018
Recall Status: Open, Classified
Recall Number: Z-2445-2018
Recall Event ID: 8031223
510(K) Number: K093914

Product Classification: Plate, fixation, bone - Product Code: HRS


Recalling Firm/Manufacturer: NewDeal SA
Immeuble Sequoia 2 97 A
97 Allée Alexandre Borodine
St Priest France

Manufacturer Reason for Recall: Use of the impacted product may cause a superficial infection requiring PO antibiotics and wound care or deep infection requiring IV antibiotics and device removal.

FDA Determined Cause: Packaging change control

Action: On May 22, 2018 Newdeal SAS, a company of Integra LifeSciences, issued URGENT VOLUNTARY MEDICAL DEVICE RECALL notices to their customers. Customers were advised to take the following actions: 1. Examine your inventory to determine if you have any affected lots in original product packaging identified within the notice. 2. If you do have any of the affected lots in original product packaging, stop using the product immediately, remove them from service and place in quarantine until the product can be returned. 3. Complete the Acknowledgement and Return Form and check the box. I do have affected products on the list and record the lot number. 4. Or, complete the attached Acknowledgement and Return Form and check the box I do not have affected products. 5. Complete the other information on the form as indicated on the form. Keep a copy of the form for your records. Return the completed Acknowledgement and Return Form by email or fax indicating your receipt and review of the notification. Customers with questions regarding the instructions, please contact Customer Service at 1-800-654-2873 Monday to Friday 8:00 AM - 8:00 PM EST or custsvcnj@integra-life.com

Distribution: CA, CO, CT, ID, KS, MA, MD, MN, MO, MS, NC, NY, OH, OR, PA, SD, VA, WA & WI

Total Product Life Cycle: TPLC Device Report

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=165161