Class 2 Device Recall DOLPHIN INFLATION DEVICE CALIBER INFLATION DEVICE

Date Initiated by Firm: April 05, 2017
Create Date: April 28, 2017
Recall Status: Open, Classified
Recall Number: Z-1891-2017
Recall Event ID: 77100
510(K) Number: K042449
Product Classification: Syringe, balloon inflation - Product Code MAV
Product: DOLPHIN INFLATION DEVICE CALIBER INFLATION DEVICE: Catalog Number: CL3030, 018SNA 018SN 018SNA 018SND; INTERNAL CODE NUMBER: 0185TR 018SNA 018SND 018SNA 018SND
Recalling Firm/Manufacturer: PEROUSE MEDICAL
ROUTE DU MANOIR
Iivy Le Temple France
Manufacturer Reason for Recall: Complaints regarding broken blister.
FDA Determined Cause: Packaging change control
Action: Consignees were notified of the recall on April 5, 2017. They were informed of the issue and asked to take the following steps: 1. Inspect your stock to determine if you still have in your ownership devices among which the references and batch codes are listed in front page; 2. Control the potential damage of the blister according to the pictures above and the instructions mentioned on the labeling and the Instruction For Use: any damaged and/or cracked blister must be immediately discarded; 3. Use the compliant products without risk after control. Indeed, the primary packaging will not deteriorate in time. If, to date, there is no crack in the blister, then the integrity of the product is not compromised; 4. Do not use the non-compliant products; 5. Complete and sign the attached reply form, then return it within 5 working days following the reception of this letter, and keep a copy; 6. Contact customer service for the modalities of return, replacement and associated support at +33 (0) 4.72.39.74.13 or by fax at +33 (0) 3.44.08.17.67 or by email at iblayon@vvgon.com (CC mhpoironre@vvgon.com); 7. Communicate the safety information to any person concerned in your company and to all end customers to which the product were transferred.
Quantity in Commerce: 18,431
Distribution: US: AZ (shipped through Belgium to USA), MN, TN
Total Product Life Cycle: TPLC Device Report