California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Olympus Corporation of the Americas Recalls EZDilate Wire Guided Balloon for Mislabeled Glo Cath Label

Recall Date	Product Description	Recalling Firm	Recall Reason
10/24/2024	EZDilate Wire Guided Balloon- Indicated for use in adult and adolescent (> 12 years) populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy. Model/Catalog Number: BD-410X-1055	Olympus Corporation of the Americas	Mislabeled Glo Cath Label (attached to the device) states: 11 mm, 12 mm, 13 mm however the balloon is 8.5mm, 9.5mm and 10.5 mm and may result in prolonged surgery. All other labeling is correct for the balloon, including the Shelf Box with Front Box Label and Circular Star Label and the balloon Pouch

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: 821925033238 Lot: 408987	209 units in Worldwide Distribution: US distribution to states of: CA, FL, IL, NJ, NY, PA, TN, VA, WI; and Foreign OUS to countries of: CA, DE, IN, SG, Latin America.	September 2024 and Prior

For additional information, please visit the FDA Website.