California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Karl Storz Endoscopy Recalls Hopkins Telescope 6 for Containing Unapproved Reprocessing Modalities

Recall Date	Product Description	Recalling Firm	Recall Reason
9/24/2024	Karl Storz - Endoskope , REF: 27092AMA, Hopkins Telescope 6, Rx only, CE 0123	Karl Storz Endoscopy	The reason for this recall is that various medical device product IFUs contain reprocessing modalities that have not been reviewed and/or approved for safety and efficacy by the FDA.

Recall Class	Product Identification	Distribution	Affected Dates
II	All Lots/UDI: (01)04048551233344	425 Units US Nationwide distribution including in the states of AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY, Puerto Rico, Guam.	September 2024 and prior

For additional information, please visit the FDA Website.