State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Karl Storz Endoscopy recalls Flexible Ureteroscope for Insufficient Sterility

Recall Date	Product Description	Recalling Firm	Recall Reason
4/01/2022	**Flexible Ureteroscope** 11278A2 11278AK2 Flexible Ureteroscope Z20615US-BA (08-2018); 11278AC1 N/A Flexible Ureteroscope Z17859US-A (04/2016); 11278AC2 11278ACK2 Flexible Ureteroscope Z20615US-BA (08-2018); 11278ACU1 11278ACUK1 Flexible Ureteroscope Z20615US-BA (08-2018); 11278AU1 11278AUK1 Flexible Ureteroscope Z20615US-BA (08-2018);	**Karl Storz Endoscopy** El Segundo, California	Failure to achieve the expected six-log reduction in microorganisms following the disinfection process.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Flexible Ureteroscope**	425 units in California	April 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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