State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Cordis US recalls Palmaz Genesis Transhepatic Biliary Stent for Potential Stent Dislodgement

Recall Date	Product Description	Recalling Firm	Recall Reason
5/20/2022	**PALMAZ GENESIS Transhepatic Biliary Stent on OPTA PRO .035" Delivery System** Catalog numbers PG2990BPS, PG2990BPX, PG3990BPS, PG3990BPX	**Cordis US Corp** Miami Lakes, Florida	Potential for stent dislodgement and associated failures related to two specific sizes of the device.

Recall Class	Product Identification	Distribution	Affected Dates
I	PG2990BPS - Lot numbers 82184806, exp. 12/31/2022; 82208532, exp. 10/31/2023. PG2990BPX - Lot numbers 82185924, exp. 1/31/2023; 82208528, exp. 10/31/2023. PG3990BPS - Lot numbers 82193089, exp. 5/31/2023; 82206059, exp. 10/31/2023. PG3990BPX - Lot numbers 82208524, exp. 11/30/2023.	18 Units in California	December 2021 – February 2022

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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