



Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Implant Direct Recalls Legacy 2 Dental Implant for Labelling Error

Recall Date	Product Description	Recalling Firm	Recall Reason
11/3/2021	Legacy 2 Implant 4.7mmD x 11.5mmL, 4.5mmD Platform REF 834711	Implant Direct Sybron Manufacturing LLC Westlake Village, California	Labelling error about Dental Implant Size
11/3/2021	Legacy 2 Implant 4.7mmD x 13mmL, 4.5mmD Platform REF 834713	Implant Direct Sybron Manufacturing LLC Westlake Village, California	Labelling error about Dental Implant Size

Recall Class	Product Identification	Distribution	Affected Dates
II	Legacy 2 Implant 4.7mmD x 11.5mmL, 4.5mmD Platform Lot # 166297 UDI: 10841307101789	61 implants Nationwide including California	September 2021 and prior
II	Legacy 2 Implant 4.7mmD x 13mmL, 4.5mmD Platform Lot # 166300 UDI: 10841307101796	83 implants Nationwide including California	September 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](https://www.fda.gov)

