California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Angiodynamics, Inc. Auryon Laser System 100-120 VAC

Recall Date	Product Description	Recalling Firm	Recall Reason
12/27/2024	AURYON LASER SYSTEM 100-120 VAC Model Number: EXM001 Product Number: EXM-2001-1100	Angiodynamics, Inc.	Potential for procedural delays or interruptions during use of the Auryon Atherectomy System due to the Auryon Atherectomy System not advancing to the Activation (Ready) mode.

Recall Class	Product Identification	Distribution	Affected Dates
II	Product Number: EXM-2001-1100 Model Number: EXM001 UDI-DI: 07290017590110 Serial Number: EXM XXX.	21 units in California	November and prior

For additional information, please visit the FDA Website.