



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Illumina Recalls MiSeq Dx and NextSeq 550 Dx for Cybersecurity Vulnerability**

Recall Date	Product Description	Recalling Firm	Recall Reason
6/22/2022	<b>MiSeq Dx</b> illumina REF DX-410-1001, 15036706, 20014053	<b>Illumina, Inc.</b> San Diego, California	cybersecurity vulnerability
6/22/2022	<b>NextSeq 550 Dx</b> REF 20005715	<b>Illumina, Inc.</b> San Diego, California	cybersecurity vulnerability

Recall Class	Product Identification	Distribution	Affected Dates
II	<b>MiSeq Dx</b> Model Numbers: DX-410-1001; 15036706; 20014053; UDI-DI Code: 00816270020002 00816270020699 All Instruments containing Software version: v.1.3.1 to 3.0 Installed Product ID: U.S.: M71006-20014737 - M71016-20014737	47 Units in California	June 2022 and prior
II	<b>NextSeq 550 Dx</b> Model Numbers: 20005715 UDI-DI Code: 00816270020125 All Instruments containing Local Run Manager (LRM) Software version: v.1.3.1 to 3.0 Installed Product ID: U.S.: NDX550779-15073937 - NDX550937-15073937	52 Units in California	June 2022 and prior

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