



**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Medtronic Recalls AMPLIA, BRAVA, CLARIA, COMPIA, EV, and VISIA Series of Implantable Cardioverter Defibrillators**

Recall Date	Product Description	Recalling Firm	Recall Reason
6/28/2023	<b>AMPLIA Series</b> Model Numbers DTMB1D1, DTMB1D4, DTMB1Q, DTMB1QQ, DTMB2D1, DTMB2D4, DTMB2Q1, DTMB2QQ	<b>Medtronic Inc.,            Cardiac Rhythm and Heart Failure (CRHF)</b> Mounds View, MD	There is a rare potential for reduced- or no-energy output during high voltage (HV) therapy (typically 0-12J) in implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured with a specific (glassed) feedthrough, including currently available ICDs and CRT-Ds.
6/28/2023	<b>BRAVA Series</b> Model Numbers: DTBC2D1, DTBC2D4, DTBC2Q1, DTBC2QQ	<b>Medtronic Inc.,            Cardiac Rhythm and Heart Failure (CRHF)</b> Mounds View, MD	There is a rare potential for reduced- or no-energy output.
6/28/2023	<b>CLARIA Series</b> Model Numbers: DTMA1D1, DTMA1Q1, DTMA1QQ, DTMA2D1, DTMA2D4, DTMA2Q1, DTMA2QQ	<b>Medtronic Inc.,            Cardiac Rhythm and Heart Failure (CRHF)</b> Mounds View, MD	There is a rare potential for reduced- or no-energy output.

6/28/2023	<b>COMPIA Series</b> Model Numbers: DTMC1D1, DTMC1QQ, DTMC2D1, DTMC2D4, DTMC2QQ	<b>Medtronic Inc., Cardiac Rhythm and Heart Failure (CRHF)</b> Mounds View, MD	There is a rare potential for reduced- or no-energy output.
6/28/2023	<b>EV ICD Series</b> Model Numbers: DVEX2E4, DVEX3E4	<b>Medtronic Inc., Cardiac Rhythm and Heart Failure (CRHF)</b> Mounds View, MD	There is a rare potential for reduced- or no-energy output.
6/28/2023	<b>VISIA Model</b> Product4 details	<b>Medtronic Inc., Cardiac Rhythm and Heart Failure (CRHF)</b> Mounds View, MD	There is a rare potential for reduced- or no-energy output.

<b>Recall Class</b>	<b>Product Identification</b>	<b>Distribution</b>	<b>Affected Dates</b>
I	<b>AMPLIA Series</b> GTIN 00643169837690; Lot Serial Numbers: RPV203851H- RPG611606S...	66,365 Units Nationwide	June 2023 and Prior
I	<b>BRAVA Series</b> GTIN 00643169720367, Lot Serial Numbers: BLW607464S- BLX610441S...	21,024 Units Nationwide	June 2023 and Prior
I	<b>CLARIA Series</b> GTIN 00643169837676, Lot Serial Numbers: RPT208454H- RPB604545S...	124,437 Units Nationwide	June 2023 and Prior
I	<b>COMPIA Series</b> GTIN 00643169837706, Lot Serial Numbers: RPW200770H- RPW200714H...	54,120 Units Nationwide	June 2023 and Prior
I	<b>EV ICD Series</b> GTIN 00763000115647, Lot Serial Numbers: EVR600484S- EVS600339S...	310 Units Nationwide	June 2023 and Prior

I	<b>VISIA Model</b> GTIN 00643169720619, Lot Serial Numbers: BWN203363H-PMX613935S...	89,360 Units Nationwide	June 2023 and Prior
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FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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