



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Medtronic Recalls Evera, Primo, Mirro, Cobalt, Crome And Viva Series Of Implantable Cardioverter Defibrillators And Cardiac Resynchronization Therapy Defibrillators**

Recall Date	Product Description	Recalling Firm	Recall Reason
6/28/2023	<b>Evera Series</b> Models: DDBB1D1, DDBB1D4, DDBB1D4G, DDBB2D1, DDBB2D4, DDBC3D1, DDBC3D4, DDMB1D1, DDMB1D4, DDMB2D1, DDMB2D4, DDMC3D1, DDMC3D4, DVBB1D1, DVBB1D4, DVBB2D1, DVBB2D4, DVBC3D1, DVBC3D4, DVMB1D4, DVMB2D1, DVMB2D4, DVMC3D1, DVMC3D4	<b>MEDTRONIC INC.,            CARDIAC RHYTHM            AND HEART            FAILURE (CRHF)</b> Mounds View, Minnesota	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>Primo Series</b> DDMD3D1, DDMD3D4	<b>MEDTRONIC INC.,            CARDIAC RHYTHM            AND HEART            FAILURE (CRHF)</b> Mounds View, Minnesota	There is a rare potential for reduced- or no-energy output
6/28/2023	<b>Mirro Series</b> DDME3D1, DDME3D4	<b>MEDTRONIC INC.,            CARDIAC RHYTHM            AND HEART            FAILURE (CRHF)</b> Mounds View, Minnesota	There is a rare potential for reduced- or no-energy output
6/28/2023	<b>Cobalt Series</b> DDPA2D1, DDPA2D1G, DDPA2D4, DDPA2D4G,	<b>MEDTRONIC INC.,            CARDIAC RHYTHM            AND HEART</b>	There is a rare potential for reduced- or no-energy output

	DDPB3D1, DDPB3D4	<b>FAILURE (CRHF)</b> Mounds View, Minnesota	
6/28/2023	<b>Crome Series</b> DDPC3D1, DDPC3D4	<b>MEDTRONIC INC., CARDIAC RHYTHM AND HEART FAILURE (CRHF)</b> Mounds View, Minnesota	There is a rare potential for reduced- or no-energy output
6/28/2023	<b>Viva Series</b> DTBA1D1, DTBA1D1G, DTBA1D4, DTBA1Q1, DTBA1QQ, DTBA1QQPG, DTBA2D1, DTBA2D1G, DTBA2D4, DTBA2Q1, DTBA2QQ, DTBA2QQG, DTBB1D1, DTBB1D4, DTBB1Q1, DTBB1QQ, DTBB2D1, DTBB2D4, DTBB2Q1, DTBB2QQ	<b>MEDTRONIC INC., CARDIAC RHYTHM AND HEART FAILURE (CRHF)</b> Mounds View, Minnesota	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>Evera Series</b> GTIN 00643169720404, Lot Serial Numbers: BWC242988H - BWC600332S ...	246196 Units Nationwide	June 2023 and prior.
I	<b>Primo Series</b> GTIN 00763000001483, Lot Serial Numbers: CWM603134S - CWM601880S	34525 Units Nationwide	June 2023 and prior.
I	<b>Mirro Series</b> GTIN 00763000001483, Lot Serial Numbers: CWM603134S - CWM601880S ...	29172 Units Nationwide	June 2023 and prior.
I	<b>Cobalt Series</b> GTIN 00763000178338, Lot Serial Numbers: RSL602442S - RSL603352S ...	118456 Units Nationwide	June 2023 and prior.

I	<b>Crome Series</b> GTIN 00763000178413, Lot Serial Numbers: RSP600249S - RSP601096S ...	8530 Units Nationwide	June 2023 and prior.
I	<b>Viva Series</b> GTIN 00643169720312, Lot Serial Numbers: BLF258142H - BLF600763S ...	17366 Units Nationwide	June 2023 and prior.

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

---

CDPH Food and Drug Branch  
MS 7602 ● P.O. Box 997435 ● Sacramento, CA 95899-7435  
(916) 650-6500 ● (916) 650-6650 FAX  
Internet Address: [www.cdph.ca.gov](http://www.cdph.ca.gov)

