



Food and Drug Branch – Drug Recalls

CALIFORNIA DRUG RECALL INFORMATION SHEET

Medtronic Recalls Harmony Delivery Catheter, Part of Transcatheter Pulmonary Valve (TPV) System, for Risk of Capsule Break During Use

Recall Date	Product Description	Recalling Firm	Recall Reason
03/02/2022	Harmony Delivery Catheter System HARMONY-DCS (GTIN: 00763000341367)	Medtronic Inc Minneapolis, Minnesota	There is potential for the capsule bond to break during the procedure.

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot Numbers: 0010519040, 0010565921, 0010578123, 0010578126, 0010583884, 0010631963, 0010631969, 0010631971, 0010717000, 0010717001, 0010717002, 0010723188, 0010723189, 0010723190, 0010727345, 0010804938, 0010826589, (the following lots were added 4/22/2022) 0010826591, 0010826592, and 0010826593	665 Devices Nationwide and Global	April 2021 – January 2022

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

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