State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Zimmer Biomet Recalls ROSA One 3.1 Brain Application Due to Error in Software

Recall Date	Product Description	Recalling Firm	Recall Reason
10/25/2021	**ROSA One 3.1 Brain Application**	**Medtech SA - Zimmer-Biomet,** Montpellier, France	Software anomaly which led to the inaccurate placement of an electrode during surgery. An incorrect trajectory could result in serious injury or death if undetected during surgery.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Serial Numbers: BS16914, BS16921, BS18943, BS18956, BS18957, BS18962, BS18983, BS18998, BS19050**	9 units in California	December, 2019 to August, 2021

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

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