

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Medimaps Group TBS Osteo TBS iNsight

Recall Date	Product Description	Recalling Firm	Recall Reason
02/28/2025	Brand Name: TBS Osteo Product Name: TBS iNsight Model/Catalog Number: TBS iNsight v3.x / pn: OS-TBSi Software Version: V3.x: (1) V3.1.2, (2) V3.1.1, (3) V3.1.0, (4)V3.0.0 Product Description: TBS iNsight is a class II Medical Device software that is installed on bone densitometers for analysis of bone microarchitecture and bone health management Component: No	Medimaps Group	Potential variability in calculations from fast array scans compared to array scans when operating on Hologic Horizon machines.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: (1) B214OSTBSI3120 (2) B214OSTBSI3110 (3) B214OSTBSIV310 (4) B214OSTBSIV300	60 software installations in California	February and prior

For additional information, please visit the [FDA Website](https://www.fda.gov).