State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Acclarent Recalls TruDi Navigation System for Discrepency between Actual Curette Tip Location and the Locatin Displayed on Navigation Systems

Recall Date	Product Description	Recalling Firm	Recall Reason
11/1/2023	**TruDi Navigation System** Model: FG-2000-00, Catalog: ENS022B, when used with TruDi Curette, Models: TDC0005Z and TDC0005	**ACCLARENT, INC.** Irvine, California	When using affected curette and software, there is a discrepancy between the actual curette tip location and the location displayed on navigation systems intended for use during surgical procedures of the Ear Nose and Throat (ENT) and ENT skull base surgery, which may cause delayed/prolonged surgery, cerebrospinal fluid leak, visual impairment, or skull base structural damage.

Recall Class	Product Identification	Distribution	Affected Dates
II	**TruDi Navigation System** UDI-DI: 10846835018639, software version: V2.3.1 Update (2.3.1.144 and 2.3.1.166)	141 Units Nationwide including California	21 September 2023 and prior

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