California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Myofunctional Research Company USA – Myosa for Kids (KS1 & KS2) Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
12/18/2025	Myosa for Kids is a pediatric mouthguard (KS1 and KS2 models) available in multiple sizes, used for children ages 3–15 to address breathing and myofunctional disorders.	Myofunctional Research Company USA Rancho Cucamonga, CA, USA	The firm distributed the device in the United States without obtaining required FDA premarket clearance/approval.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Lot Code:** N/A **Model No.:** KS1 REF MyOSAKS1_Sb/Sp/Mb/Mp/Lb/Lc; KS2 REF MyOSAKS2_Sb/Sc/Mb/Mc/Mp/Lb/Lc **UDI-DI:** N/A **S/N range:** N/A	436 Units; Nationwide including California (7 units in CA)	October 2025 and prior.

For additional information, please visit the FDA Website.