State of California—Health and Human Services Agency
California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Wavi Co. Recalls Wavi Research EEG Desktop System

Recall Date	Product Description	Recalling Firm	Recall Reason
5/31/2024	**Wavi Research EEG Desktop System** WAVi Research EEG Desktop System is comprised of the WAVi Research EEG Desktop Software with Instruction Manual and Brochure, and Heart Rate Variability (HRV) Ear Clips. The system kit also incorporates use of the firm's cleared EEG analysis technology (the WAVi SCAN EEG System and Accessories, and the WAVi Headset and eSoc Single Use Electrode Contacts).	**WAVI CO.** Denver, Colorado	Following an FDA-issued Warning Letter, the firm requested return of their research EEG system components due to the closing of their research study.

Recall Class	Product Identification	Distribution	Affected Dates
II	**Wavi Research EEG Desktop System** Desktop software version 1.0.0.2	23 Units in California	May 2024 and prior.

For additional information, please visit the FDA website.

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