California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Nihon Kohden America Inc Recall Adult/Pediatric Forehead Disposable SpO2 Sensor and Adult Ear Clip SpO2 Sensor

Recall Date	Product Description	Recalling Firm	Recall Reason
10/30/2024	Nihon Kohden Adult/Pediatric Forehead Disposable SpO2 Sensor, 0.9m Model 809030006 Disp. SpO2 Forehead Probe, Adult, 10/Box Nihon Kohden Adult Ear Clip SpO2 Sensor, 1.5 meter Model 809030007 Reusable SpO2 Ear Clip, each	Nihon Kohden America Inc	Due to oximeters not having FDA market approval or clearance to distribute in the U.S.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model num.: 809030006 UDI-DI: 06970758500173 All lot numbers Model num.: 809030007 UDI-DI: 06970758500159 All lot numbers	1 box of SpO2 forehead sensor A/809030006 shipped to one customer within CA 15 units in California	September 2024 and Prior

For additional information, please visit this FDA Website Forehead Disposable SpO2 Sensor and this FDA Website Adult Ear Clip SpO2 Sensor.