



## CALIFORNIA DEVICE RECALL INFORMATION SHEET

### GE Healthcare Finland Oy TruSignal Ear Sensor for Reduction of Energy

Recall Date	Product Description	Recalling Firm	Recall Reason
7/12/2023	<b>TruSignal Ear Sensor</b> REF TS-E-D; Oximeter	<b>GE Healthcare Finland Oy</b> Finland	There is a potential reduction of energy reaching patient during defibrillation, potential contact with unintended voltage, or inaccurate measurement.
7/12/2023	<b>TruSignal Integrated Ear Sensor with GE Connector</b> REF TS-E2-GE; Oximeter, Ear	<b>GE Healthcare Finland Oy</b> Finland	There is a potential reduction of energy reaching patient during defibrillation, potential contact with unintended voltage, or inaccurate measurement.
7/12/2023	<b>TruSignal Integrated Ear Sensor with Datex Connector</b> REF TS-E4-GE; Monitor, physiological, patient (with arrhythmia detection or alarms); REF TS-E4-N; Oximeter	<b>GE Healthcare Finland Oy</b> Finland	There is a potential reduction of energy reaching patient during defibrillation, potential contact with unintended voltage, or inaccurate measurement.
7/12/2023	<b>TruSignal Integrated Ear Sensor with Ohmeda Connector</b> REF TS-E4-H; Oximeter	<b>GE Healthcare Finland Oy</b> Finland	There is a potential reduction of energy reaching patient during defibrillation, potential contact with unintended voltage, or inaccurate measurement.

<b>Recall Class</b>	<b>Product Identification</b>	<b>Distribution</b>	<b>Affected Dates</b>
I	<b>TruSignal Ear Sensor</b> GTIN 00840682103251	10,451 Units Nationwide	May 2023 and Prior
I	<b>TruSignal Integrated Ear Sensor with GE Connector</b> GTIN 00840682103138	512 Units Nationwide	May 2023 and Prior
I	<b>TruSignal Integrated Ear Sensor with Datex Connector</b> GTIN 00840682103428; 00840682103381	3,415 Units Nationwide	May 2023 and Prior
I	<b>TruSignal Integrated Ear Sensor with Ohmeda Connector</b> GTIN 00840682103367	237 Units Nationwide	May 2023 and Prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE [FDA WEBSITE](#)

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