FDA clears Ikaria's upgraded neonate drug delivery system

Mass Device

Healthcare products maker Ikaria wins FDA 510(k) clearance for a software upgrade for its Inomax DSIR system.

Hampton, N.J.-based healthcare company Ikaria won FDA clearances for an upgraded software package and 3 non-invasive respiratory care devices for use with its Inomax DSIR drug delivery system.

The Inomax DS and DSIR deliver the company's proprietary Inomax vasodilator solution, which the company calls the only FDA-approved drug for treatment of infant hypoxic respiratory failure, associated with pulmonary hypertension.