

## **FDA clears Masimo devices for newborn heart disease screening**

Mass Device

Masimo wins 510(k) clearance to expand its oximeters and neonatal sensors to screen newborns for critical congenital heart disease.



[Masimo](#) [1] (NSDQ:[MASI](#) [2]) landed FDA 510(k) clearance to expand its pulse oximeters and neonatal sensors to screen newborns for signs of critical congenital heart disease.

The devices, which include Masimo's SET pulse oximeters and Rainbow SET pulse co-oximeters, were previously cleared for measuring oxygen saturation levels and pulse rate in newborns, but the new labeling provides specific indication for use during physical CCHD screening, according to a press release.

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[http://www.mdtmag.com/news/2012/09/fda-clears-masimo-devices-newborn-heart-disease-screening?qt-video\\_of\\_the\\_day=0&qt-recent\\_content=0](http://www.mdtmag.com/news/2012/09/fda-clears-masimo-devices-newborn-heart-disease-screening?qt-video_of_the_day=0&qt-recent_content=0)

**Links:**

[1] <http://www.massdevice.com/company/masimo>

[2] <http://www.google.com/finance?q=masi>