Recall: Nidek pulls oxygen concentrators over nursing home fires | Regulatory Roundup

Mass Device

Oxygen devices maker Nidek recalls its Mark5 Nuvo products after receiving reports of fires in residences and nursing homes.

[1] House, nursing home fires spur Nidek oxygen concentrator recall **[2]**
Alabama-based oxygen devices maker Nidek Medical pulled its Mark5 Nuvo oxygen concentrators off of shelves after receiving reports of fires in homes and nursing homes, according to an FDA release.

The company pulled 8 Mark 5 models after finding that a capacitor component in some devices failed and "resulted in residential and nursing home fires," as well as failing to provide oxygen.

The recall has been given "Class I" status from the FDA, reserved for the highest risk recalls that are likely to result in patient injury or death.

The oxygen concentrator devices are not considered life-supporting, and no injuries have been reported to date, according to the release.
Read more **[2]**

[1] MicroMed wins IDE approval to launch a clinical trial of its HeartAssist 5 **[3]**
Houston, Texas-based MicroMed Cardiovascular won FDA investigational device exemption to launch human trials of its next-generation HeartAssist 5 left-ventricular assist device in up to 192 patients.
Read more **[3]**

Source URL (retrieved on *07/11/2014 - 10:02am*):
http://www.mdtmag.com/news/2012/06/recall-nidek-pulls-oxygen-concentrators-

over-nursing-home-fires-regulatory-roundup?qt-video_of_the_day=0

Links:
[1] http://www.massdevice.com/
[2] http://www.fda.gov/Safety/Recalls/ucm308840.htm
[3] http://www.marketwire.com/press-release/a-milestone-for-micromed-cardiovascular-1669582.htm