



Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: June 20, 2012
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: 
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Nidek Medical Products, Inc. Recall

SUGGESTED ACTION: Class I Recall; Capacitor-related fires in Medical Mark5 Nuvo Lite Oxygen concentrators as a Class I recall; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled product may have been distributed in the State of Indiana. The affected devices were manufactured and distributed from January 2004 through May 2010 with serial numbers in the range of 042-10000 through 102-09335. The reason for the field correction is due to a capacitor component inside the concentrators found in some instances to fail, which has resulted in residential and nursing home fires, and loss of supplemental oxygen supply. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-351-7190.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Nidek Medical Products, Inc. issues an Urgent Medical Device Correction affecting oxygen concentrators.

Contact:
Consumer:
1-205-856-7200 ext 242

FOR IMMEDIATE RELEASE - June 18, 2012 - Models Affected: Nidek Medical Products, Inc., oxygen concentrator models

1. Nidek Medical Mark5 Nuvo / M5C5 Std, 115 V ~60Hz – 410W
2. Nidek Medical Mark5 Nuvo / M5C5 Std, 230 V ~50/60Hz – 420W
3. Nidek Medical Mark5 Nuvo / M5C5 OCSI, 115 V ~50/60Hz – 410W
4. Nidek Medical Mark5 Nuvo / M5C5 OCSI, 230 V ~50/60Hz – 420W
5. Nidek Medical Mark5 Nuvo 8 Std, 115 V ~60Hz – 500W
6. Nidek Medical Mark5 Nuvo 8 OCSI, 230 V ~50/60Hz – 420W
7. Nidek Medical Mark5 Nuvo Lite Model 520 Std, 115 V ~60Hz – 330W
8. Nidek Medical Mark5 Nuvo Lite Model 525 OCSI, 115 V ~60Hz – 330W
9. Nidek Medical Mark5 Nuvo Lite Model 920 Std, 230 V ~60Hz – 330W
10. Nidek Medical Mark5 Nuvo Lite Model 925 OCSI, 230 V ~50Hz – 300W
11. Nidek Medical Mark5 Nuvo Lite Model 925/60 OCSI, 230 V ~60Hz – 280W

Nidek Medical Products, Inc., today announced that the U.S. Food and Drug Administration (FDA) has classified Nidek's voluntary recall action regarding capacitor-related fires in Medical Mark5 Nuvo Lite Oxygen concentrators as a Class I recall. The affected devices were manufactured and distributed from January 2004 through May 2010 with serial numbers in the range of 042-10000 through 102-09335. The reason for the field correction is due to a capacitor component inside the concentrators found in some instances to fail, which has resulted in residential and nursing home fires, and loss of supplemental oxygen supply. There have been no reports of injury to date.

Use: Oxygen concentrators are normally used to supply supplemental oxygen to patients within a home setting. They are not considered to be life supporting devices.

Nidek Medical Products, Inc., is in the process of notifying all of its distributors and customers by email and regular mail as necessary and is arranging to supply replacement capacitors for all affected devices as available.

To date, recipients of more than 95 percent of affected concentrators have been notified. The Food and Drug Administration is aware of this action and receives reports of its progress.

Public Contact: Consumers should notify their equipment providers if they have an affected product in their home or place of business. Patients may continue to use the device while waiting for correction. Consumers with questions may contact Nidek Medical Products, Inc. at 1-205-856-7200 ext 242 or by email at fieldcorrection@nidekmedical.com.

Any adverse experience with the use of these products may be reported to the FDA at 1-800-FDA-1088 or online at <http://www.fda.gov/safety/Medwatch/HowToReport/default/htm>¹ to obtain a form to fax or mail.

###