

Safety Communication

ElectroMist - Potential for failed stability antimicrobial effectiveness testing

Device/ Product Description:	ElectroMist
Brand Name:	ElectroMist
Lot numbers/Serials:	ElectroMist product codes: 36-3310-04 Lot # 030215-04, 011716-04, 072816-04, 072816-04, 071618-04, 080117-04
Manufacturer:	Pharmaceutical Innovations, Inc.
Problem:	Potential for failed stability antimicrobial effectiveness testing.
Recommendation/ Actions:	<ul style="list-style-type: none"> • Customers were instructed to do the following: <ol style="list-style-type: none"> 1. Examine inventory, Isolate and quarantine these products. 2. Notify any end users, customers or additional facilities within your organization to discontinue use and sale and quarantine those products until final disposition has been determined and performed. 3. All LOD (Letter of Destruction) requests must be accompanied by photographs of actual product to receive credit and or reimbursement. • You can find more information and recommendations from (Here).
Devices/Products photo:	

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should **report any adverse events** suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector

Saudi Food and Drug Authority

Postal Address: Saudi Arabia - Saudi Food and Drug Authority

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Or

Saudi Vigilance

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Sincerely,
NCMDR Team