Monroe Livingston Region Program Agency

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To: All MLREMS ALS/ILS Agencies

From: Jeremy T. Cushman, MD, MS, EMT-P
Regional Medical Director

Date: 12-04-09

Re: MLREMS Advisory 09-08: King LTS-D

In an October 26 letter to the King Systems, Inc, the manufacturer of the King Airway, the FDA identified that the King LTS-D has not received marketing clearance or approval and is in violation of the Food, Drug and Cosmetic Act. The FDA Office of Compliance has requested that King Systems immediately cease advertising the King LTS-D until properly approved by the FDA.

This is neither a recall nor an order to stop selling the device, simply an order to stop making claims in their marketing materials. As neither King Systems nor the FDA has issued a recall of the device, agencies that have the King LTS-D may continue to use it.

The King Airway remains the alternative airway of choice in the Monroe-Livingston Region, however the King LT and LT-D remain preferred over the King LTS-D notwithstanding the marketing technicality cited by the FDA.

With any questions, do not hesitate to contact the MLREMS Program Agency via the University of Rochester, Division of Prehospital Medicine.