



# State of New Hampshire

## Department of Safety

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Robert L. Quinn  
Commissioner

Justin A. Cutting  
Director

# CLINICAL BULLETIN

Bulletin #	Title			Date Issued
83	Pediatric KING-LTS-D Airway			September 28, 2023
Superseded	Released By	Approved By	Source	For More Information
	FSTEMS	Chief Romanello	FDA	FST/EMS (603) 223-4200

In a letter dated August 16, 2023 to Steven Block, President & CEO, King Systems Corp. dba Ambu, Inc. the FDA stated that the King LTS-D branded supraglottic airway with gastric access lumen for pediatrics does not have an approved application for premarket. This raises questions of safety and effectiveness that may lead to patient adverse events in the pediatric population. The FDA ordered the King Systems Corp. dba Ambu, Inc. to remove their unsupported performance claim from their website or provide a 510(k) with proposed indication for use.

All licensed EMS units that are stocking this piece of equipment are encouraged to remove this device from their inventory immediately based on it not being approved for use by the FDA.

This letter can be found at: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/king-systems-corp-dba-ambu-inc-661617-08162023>