



# Inland Counties Emergency Medical Agency

*Serving San Bernardino, Inyo, and Mono Counties*

*Virginia Hastings, Executive Director  
Reza Vaezazizi, M.D., Medical Director*

**DATE:** December 18, 2009

**TO:** Steven Tharratt, MD, EMSA Medical Director  
ICEMA Region ALS and BLS Providers  
Base Hospital Medical Directors, PLNs  
Medical Advisory Committee, EMCCs

**FROM:** Reza Vaezazizi, MD  
ICEMA Medical Director

**SUBJECT: CLARIFICATION OF FDA KING AIRWAY WARNING**

Recently, the Food and Drug Administration (FDA) issued a warning letter to King Systems concerning their marketing and advertisement of the King LTS-D airway to EMS providers. This letter has generated significant concern in our region about the use of this device in the prehospital setting. ICEMA Administration has carefully reviewed this letter, and has discussed this matter with Dr. Steven Tharratt, Medical Director of the California EMS Authority, as well as the Medical Advisory Committee (MAC) members from within the ICEMA region.

Dr. Tharratt reiterated that the letter is directed at the company and the concerns of their marketing practices, not EMS's use of the device. In addition, he has indicated that this letter does not change the approval of King Airway as an approved optional scope device for paramedics and EMTs in the State of California.

Moreover, this issue was discussed at length at the December 16, 2009 Medical Advisory Committee Meeting. MAC Members voted unanimously in strong support of ICEMA's moving forward with the January 1, 2010 implementation date.

It is important to understand that the FDA's concern is with how the device is marketed by vendors, not how it is used. There is strong consensus that King Airway device is safe and likely superior to other available alternatives. In the United States, the Food and Drug Administration regulations permit the use of approved devices and medications for other than their intended indications. This practice is known as "Off-Label" use. The use of the King Airway device in the prehospital airway management is an example of such use. "Off-Label" use of approved devices and medications is common within the medical community and is entirely legal. However, current FDA regulations prohibit the manufactures from advertising or promoting any possible "Off-Label" use for their medical devices.

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EMS providers are advised that the current timeline to implement the use of King Airway device by all ALS providers in ICEMA region by January 1, 2010 remains unchanged. The device also remains available for BLS providers as an optional local scope item, which requires a separate application and approval by ICEMA. Please contact Sherri Shimshy at (909) 388-5816 or [sshimshy@cao.sbcounty.gov](mailto:sshimshy@cao.sbcounty.gov) should you have any questions. Thank you.

RV/jch

c: Virginia Hastings, ICEMA Executive Director  
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