

**K090915 STERILE WATER FOR INHALATION FLEX BAG, USP**Nov 18, 2009  
231 days to decisionK090915 · Product code: **BTT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k090915/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Apr 1, 2009
Decision date	Nov 18, 2009
Days to decision	231 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardinal Health, Inc.</b>
Location	Waukegan, IL, US
Contact	KIMBERLY SOUTHWELL
Website	<a href="http://www.cardinalhealth.com">http://www.cardinalhealth.com</a>
510(k) history	26 submissions · 26 cleared · 2006-2017

Cardinal Health, Inc. is an American multinational health care services company headquartered in Dublin, Ohio. The company specializes in pharmaceutical distribution and medical product manufacturing, serving over 100,000 locations across the United States. Cardinal Health has received FDA 510(k) clearances from total submissions between 2006 and 2017. The company's regulatory focus centers on surgical gloves and protective apparel, including sterile and powder-free formulations. This historical record reflects the company's established presence in General Hospital device...

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