

**K063758 CHONCHA THERM NEPTUNE HEATED HUMIFIER,  
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(REMANUFACTURER), MODEL# 425-00,425-00R**Apr 23, 2007  
125 days to decisionK063758 · Product code: **BTT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k063758/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Dec 19, 2006
Decision date	Apr 23, 2007
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Teleflex Medical</b>
Location	Fall River, MA, US
Contact	LORI HAYS
510(k) history	39 submissions · 39 cleared · 2003-2025

Teleflex Medical is an American medical device company headquartered in Wayne, Pennsylvania, with operations in Fall River, US. The company is a major provider of specialty medical devices for critical care and surgical procedures. Teleflex Medical has received FDA 510(k) clearances from total submissions since 2003. The company maintains active regulatory engagement, with the latest clearance in 2025. Its cleared devices span multiple specialties including anesthesiology, general and plastic surgery, cardiovascular, and vascular access systems. The company's product port...