

**K223551 Sterile Water for Inhalation in 1L Flexoval ® bottles.**Aug 3, 2023  
251 days to decisionK223551 · Product code: **BTT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k223551/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Nov 25, 2022
Decision date	Aug 3, 2023
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hometa, Inc.</b>
Location	Albany, NY, US
Contact	Raza Mohammed
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223551/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026