

K253322 Hudson RCI® Infant Dri-Tech™ Breathing Circuits (HUD99060 / Dri-Tech with 78” Infant Circuit, HUD99060KIT / Dri-Tech with 78” Infant Circuit Kit, HUD99001KIT / Single Limb Infant Circuit Dri-Tech Kit, HUD99009KIT / Dri-Tech with 60” Infant Circuit Kit, HUD99018KIT / Dri-Tech with 44” Infant Circuit Kit, HUD870NKIT / Dri-Tech Infant Accessory Bag, HUD1631 / Infant Wye Connector with Swivel)

Mar 25, 2026
176 days to decision

K253322 · Product code: **BZE** · Anesthesiology
Source: <https://www.510kdatabase.net/k253322/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heater, Breathing System W/wo Controller (not Humidifier Or Nebulizer (BZE)
Date received	Sep 30, 2025
Decision date	Mar 25, 2026
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, LP
Location	Nortfield, IL, US
Contact	Phyllis Kondor
Website	https://www.medline.com
510(k) history	29 submissions · 29 cleared · 2022-2026
