

K250312 Hudson RCI® Comfort Flo Nasal Cannula Premature, Infant

Jul 2, 2025
149 days to decision

K250312 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k250312/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Feb 3, 2025
Decision date	Jul 2, 2025
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Hudson RCI® Comfort Flo Plus and Soft Plus Cannula Extra Small

APPLICANT

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