

**K243820 Hoover Negative Pressure Access Sheath (Hoover)
(Hoover Model #'s IVX-NS-1040, IVX-NS-1050, IVX-
NS-1140, IVX-NS-1150, IVX-NS-1240, IVX-NS-1250**Jan 31, 2025
50 days to decisionK243820 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k243820/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Dec 12, 2024
Decision date	Jan 31, 2025
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dornier Medtech America
Location	Kennesaw, GA, US
Contact	John Hoffer
510(k) history	6 submissions · 6 cleared · 2013-2025

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