

K242931 HFT750UMay 15, 2025
232 days to decisionK242931 · Product code: **MNT** · Anesthesiology
Source: <https://www.510kdatabase.net/k242931/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use (MNT)
Date received	Sep 25, 2024
Decision date	May 15, 2025
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mekics Co., Ltd.
Location	Gyeonggi-Do, KR
Contact	Sang-Hag Lee
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov
