

K250298 Kiwi® Complete Vacuum Delivery System, OmniCup® (VAC-DUAL M)

Oct 8, 2025
250 days to decision

K250298 · Product code: **HDB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k250298/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractor, Vacuum, Fetal (HDB)
Date received	Jan 31, 2025
Decision date	Oct 8, 2025
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Kiwi® Complete Vacuum Delivery System, OmniCup® with Traction Force Indicator (VAC-DUAL MT); Kiwi® Complete Vacuum Delivery System, OmniC Cup® for Cesarean Section (VAC-DUAL C); Kiwi® Complete Vacuum Delivery System, ProCup® (VAC-DUAL S)

APPLICANT

Company	Clinical Innovations, LLC
Location	Murray, UT, US
Contact	Alexis Ross
510(k) history	9 submissions · 9 cleared · 2007-2025
