

K243384 Belzer UW® Cold Storage Solution (BTLBUW-001)Mar 31, 2025
151 days to decisionK243384 · Product code: **KDN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k243384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	Oct 31, 2024
Decision date	Mar 31, 2025
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bridge TO Life
Location	Northbrook, IL, US
Contact	Mark Harper
510(k) history	3 submissions · 3 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243384/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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