

**K192869 SherpaPak Lung Preservation System , SherpaPak
Liver Transport System**Jan 16, 2020
101 days to decisionK192869 · Product code: **KDN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k192869/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	Oct 7, 2019
Decision date	Jan 16, 2020
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Pragonix Technologies
Location	Braintree, MA, US
Contact	Lisa Anderson
510(k) history	1 submissions · 0 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Northstar Biomedical Associates
Contact	Leo Basta

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

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