

K202125 Century Perfusion SystemMar 7, 2021
219 days to decisionK202125 · Product code: **DTQ** · CardiovascularSource: <https://www.510kdatabase.net/k202125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	Jul 31, 2020
Decision date	Mar 7, 2021
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Century Hlm, LLC
Location	Mesa, AZ, US
Contact	Jeff Poland
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Vaibhav Arvind Rajal

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202125/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026