

K201642 Paragon Adult Maxi PMP Oxygenator with Tubing PackSep 18, 2020
93 days to decisionK201642 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k201642/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jun 17, 2020
Decision date	Sep 18, 2020
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chalice Medical , Ltd.
Location	Worksop, GB
Contact	Stephen Horan
510(k) history	3 submissions · 3 cleared · 2020-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201642/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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