

K200109 OXY-1 SystemOct 23, 2020
280 days to decisionK200109 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k200109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jan 17, 2020
Decision date	Oct 23, 2020
Days to decision	280 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abiomed, Inc.
Location	Danvers, MA, US
Contact	Steve Orwig
Website	http://www.abiomed.com/
510(k) history	19 submissions · 17 cleared · 1989-2025

Abiomed, Inc. develops innovative cardiovascular devices focused on native heart recovery. Founded in 1981, the company specializes in percutaneous heart pump technology and related support systems. Now part of Johnson & Johnson, Abiomed operates with a manufacturing facility in Danvers, Massachusetts. Abiomed has received FDA 510(k) clearances from total submissions since 1989. Cardiovascular devices represent 84% of the company's regulatory portfolio. The company remains active, with the latest clearance in 2025, demonstrating continued innovation and market presence. T...
