FDA 510(k) Premarket Notification

K992559 HOLLOW FIBER MEMBRANE OYGENATOR QUADROX HMO 1010

CLEARED

Sep 20, 1999
52 days to decision

K992559 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k992559/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 30, 1999
Decision date	Sep 20, 1999
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Jostra Bentley**
Location	Austin, TX, US
Contact	KATHY JOHNSON
510(k) history	3 submissions · 3 cleared · 1995-1999