FDA 510(k) Premarket Notification

K023381 VISION HOLLOW FIBER OXYGENATOR WITH GUARDIAN COATING

CLEARED

Mar 31, 2003
174 days to decision

K023381 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k023381/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Oct 8, 2002
Decision date	Mar 31, 2003
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gish Biomedical, Inc.**
Location	Mchenry, IL, US
Contact	J. HARVEY KNAUSS
510(k) history	75 submissions · 75 cleared · 1983-2009