FDA 510(k) Premarket Notification

CLEARED

K082403 MEDOS HILITE OXYGENATOR, MODEL 7000 & 7000 LT

May 15, 2009
267 days to decision

K082403 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k082403/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Aug 21, 2008
Decision date	May 15, 2009
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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