FDA 510(k) Premarket Notification

K041650 MICRO PRIME

CLEARED

Aug 16, 2004
60 days to decision

K041650 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k041650/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jun 17, 2004
Decision date	Aug 16, 2004
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Innovx Medical, Inc.**
Location	Stillwater, MN, US
Contact	ELAINE DUNCAN
510(k) history	1 submissions · 1 cleared · 2004-2004