FDA 510(k) Premarket Notification

CLEARED

K061171 SEQUITOR STEERABLE GUIDEWIRE, MODELS SQR18XX AND SQR14XX

Jun 2, 2006
36 days to decision

K061171 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k061171/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Apr 27, 2006
Decision date	Jun 2, 2006
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biosphere Medical, Inc.**
Location	Rockland, MA, US
Contact	ROSINA ROBINSON
510(k) history	6 submissions · 6 cleared · 2001-2012