FDA 510(k) Premarket Notification

K091780 GUIDED MEASUREMENT CATHETER (GMC)

CLEARED

Oct 16, 2009
121 days to decision

K091780 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k091780/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jun 17, 2009
Decision date	Oct 16, 2009
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mediguide, Ltd.**
Location	Washington, DC, US
Contact	JONATHAN S KAHAN
510(k) history	3 submissions · 3 cleared · 2009-2010