FDA 510(k) Premarket Notification

K062769 PRESSUREWIRE CERTUS, MODELS 12006 AND 12306

CLEARED

Dec 4, 2006
80 days to decision

K062769 · Product code: **DXO** · Cardiovascular
Source: https://www.510kdatabase.net/k062769/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	Sep 15, 2006
Decision date	Dec 4, 2006
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Radi Medical Systems AB**
Location	Uppsala, SE
Contact	MATS GRANLUND
510(k) history	24 submissions · 24 cleared · 1990-2013