FDA 510(k) Premarket Notification

K031810 AMPLATZER VASCULAR PLUG

CLEARED

Sep 9, 2003
89 days to decision

K031810 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k031810/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jun 12, 2003
Decision date	Sep 9, 2003
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Aga Medical Corp.**
Location	Plymouth, MN, US
Contact	PATRICE M STROMBERG
510(k) history	14 submissions · 14 cleared · 2000-2012

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k031810/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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