FDA 510(k) Premarket Notification

K993248 AMPLATZER SIZING BALLOON

CLEARED

Jul 12, 2000
288 days to decision

K993248 · Product code: **MJN** · Cardiovascular
Source: https://www.510kdatabase.net/k993248/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Sep 28, 1999
Decision date	Jul 12, 2000
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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