

K912635 ANNULUS DISPOSABLE VALVULOTOMEOct 18, 1991
126 days to decisionK912635 · Product code: **MGZ** · CardiovascularSource: <https://www.510kdatabase.net/k912635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valvulotome (MGZ)
Date received	Jun 14, 1991
Decision date	Oct 18, 1991
Days to decision	126 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cardio Source
Location	Malibu, CA, US
Contact	STEPHEN COOKSTON
510(k) history	2 submissions · 2 cleared · 1991-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912635/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 6, 2026