FDA 510(k) Premarket Notification

K870186 ENDOMYOCARDIAL BIOPSY DEVICE

CLEARED

Feb 20, 1987
35 days to decision

K870186 · Product code: **DWZ** · Cardiovascular
Source: https://www.510kdatabase.net/k870186/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Biopsy, Endomyocardial (DWZ)
Date received	Jan 16, 1987
Decision date	Feb 20, 1987
Days to decision	35 days
Third-party review	No

APPLICANT

Company	**Mansfield Scientific, Inc.**
Location	Walker, MI, US
Contact	BRUCE BEAUCHEMIN
510(k) history	8 submissions · 8 cleared · 1984-1987