FDA 510(k) Premarket Notification

K903840 GIANT LUMEN SAFETIP SERIES: ENDOMYOCARDIAL BIOPSY

CLEARED

Oct 16, 1990
56 days to decision

K903840 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k903840/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 21, 1990
Decision date	Oct 16, 1990
Days to decision	56 days
Third-party review	No

APPLICANT

Company	**Intec Medical, Inc.**
Location	Blue Springs, MO, US
Contact	KENNETH SPECTOR
510(k) history	17 submissions · 17 cleared · 1980-1991