FDA 510(k) Premarket Notification

K924712 ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM

CLEARED

Dec 8, 1992
81 days to decision

K924712 · Product code: **MCW** · Cardiovascular
Source: https://www.510kdatabase.net/k924712/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Sep 18, 1992
Decision date	Dec 8, 1992
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hearing Tech, Inc.**
Location	Minnetonka, MN, US
Contact	LOUISE C MYERS
510(k) history	11 submissions · 11 cleared · 1985-1994