FDA 510(k) Premarket Notification

K960379 ROTABLATOR SYSTEM'S GUIDE WIRE LINE: SUPPORT ROTAWIRE RAIL ROTA WIRE

CLEARED

Apr 25, 1996
90 days to decision

K960379 · Product code: **MCW** · Cardiovascular
Source: https://www.510kdatabase.net/k960379/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Jan 26, 1996
Decision date	Apr 25, 1996
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Heart Technology Mfg., Inc.**
Location	Redmond, WA, US
Contact	DIANE JOHNSON
510(k) history	3 submissions · 3 cleared · 1995-1996