FDA 510(k) Premarket Notification

K880194 KENSEY CATHETER

CLEARED

Apr 18, 1988
90 days to decision

K880194 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k880194/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jan 19, 1988
Decision date	Apr 18, 1988
Days to decision	90 days
Third-party review	No

APPLICANT

Company	**Theratek, Inc.**
Location	Miami, FL, US
Contact	FURST, B.S.
510(k) history	1 submissions · 1 cleared · 1988-1988