

**K880194 KENSEY CATHETER**Apr 18, 1988  
90 days to decisionK880194 · 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	<b>Theratek, Inc.</b>
Location	Miami, FL, US
Contact	FURST, B.S.
510(k) history	1 submissions · 1 cleared · 1988-1988

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k880194/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 7, 2026