

K962638 TONOCAP, TC-200 AND ACCESSORY CATHETERSApr 4, 1997
273 days to decisionK962638 · Product code: **CCK** · Anesthesiology
Source: <https://www.510kdatabase.net/k962638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Jul 5, 1996
Decision date	Apr 4, 1997
Days to decision	273 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Instrumentarium Corp.
Location	Tewksbury, MA, US
Contact	JOEL KENT
510(k) history	20 submissions · 20 cleared · 1983-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k962638/> Data sourced from FDA 510(k) public records (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. - Generated May 19, 2026