

K003020 CARDIAC FUNCTION LABORATORYMay 11, 2001
226 days to decisionK003020 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k003020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Sep 27, 2000
Decision date	May 11, 2001
Days to decision	226 days
Third-party review	No
Summary / Statement	Summary
Other names	PRESSURE INTERFACE; PRESSURE / VOLUME CATHETER

APPLICANT

Company	Cd Leycom BV
Location	Zoetermeer, NL
Contact	TIM LENIHAN
510(k) history	3 submissions · 3 cleared · 2001-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003020/> 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 July 3, 2026