

K870976 ONGUARD 1000, CATALOG #043611-000 & 043611-001May 6, 1987
57 days to decisionK870976 · Product code: **DTQ** · Cardiovascular
Source: <https://www.510kdatabase.net/k870976/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Console, Heart-lung Machine, Cardiopulmonary Bypass (DTQ)
Date received	Mar 10, 1987
Decision date	May 6, 1987
Days to decision	57 days
Third-party review	No

APPLICANT

Company	Cobe Laboratories, Inc.
Location	Mchenry, IL, US
Contact	VERA BUFFALOE
Website	https://www.gambro.com
510(k) history	77 submissions · 77 cleared · 1976-1993

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