

K974320 CRYOGEN CARDIAC CRYOSURGICAL SYSTEMFeb 3, 1998
78 days to decisionK974320 · Product code: **OCL** · Cardiovascular
Source: <https://www.510kdatabase.net/k974320/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Device, For Cutting, Coagulation, And/or Ablation Of Tissue, Including Cardiac Tissue (OCL)
Date received	Nov 17, 1997
Decision date	Feb 3, 1998
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cryogen, Inc.
Location	San Diego, CA, US
Contact	CHERYL L SHEA
510(k) history	4 submissions · 3 cleared · 1997-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974320/> 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