

K883452 ACS INDEFLATOR P/T 20Oct 14, 1988
63 days to decisionK883452 · Product code: **DXT** · Cardiovascular
Source: <https://www.510kdatabase.net/k883452/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Aug 12, 1988
Decision date	Oct 14, 1988
Days to decision	63 days
Third-party review	No

APPLICANT

Company	Advanced Cardiovascular Systems, Inc.
Location	Santa Clara, CA, US
Contact	KEVYN B O'CONNOR
510(k) history	103 submissions · 100 cleared · 1982-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k883452/>; 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 1, 2026