FDA 510(k) Premarket Notification

K913847 SYSTEM 90 AND SYSTEM 90T

CLEARED

Mar 11, 1992
197 days to decision

K913847 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k913847/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Balloon, Intra-aortic And Control (DSP)
Date received	Aug 27, 1991
Decision date	Mar 11, 1992
Days to decision	197 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Datascope Corp.**
Location	Mchenry, IL, US
Contact	ARTHUR FRIEDMAN
510(k) history	136 submissions · 135 cleared · 1976-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k913847/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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