FDA 510(k) Premarket Notification

CLEARED

K991775 MODIFICATION TO COMPUTERIZED CATHETERIZATION LABORATORY - HORIZON 9000 WS

Jun 24, 1999
30 days to decision

K991775 · Product code: **DXG** · Cardiovascular
Source: https://www.510kdatabase.net/k991775/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	May 25, 1999
Decision date	Jun 24, 1999
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mennen Medical, Inc.**
Location	Clarence, NY, US
Contact	KENNETH RAICHMAN
510(k) history	34 submissions · 34 cleared · 1985-2004