FDA 510(k) Premarket Notification

K032997 MODIFICATION TO: HORIZON 9000WS

CLEARED

Oct 15, 2003
20 days to decision

K032997 · Product code: **DXG** · Cardiovascular
Source: https://www.510kdatabase.net/k032997/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Sep 25, 2003
Decision date	Oct 15, 2003
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mennen Medical , Ltd.**
Location	Rehovot, IL
Contact	EREZ NIMROD
510(k) history	21 submissions · 21 cleared · 2000-2015