FDA 510(k) Premarket Notification

K922136 ULTRA+ BLOOD GLUCOSE MONITORING TEST STRIP

CLEARED

Aug 10, 1993
475 days to decision

K922136 · Product code: **CGA** · Chemistry
Source: https://www.510kdatabase.net/k922136/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Apr 22, 1992
Decision date	Aug 10, 1993
Days to decision	475 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Home Diagnostics, Inc.**
Location	Eatontown, NJ, US
Contact	Maureen Garner
510(k) history	22 submissions · 22 cleared · 1985-2009