FDA 510(k) Premarket Notification

K981911 PROFA

CLEARED

Nov 12, 1998
164 days to decision

K981911 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k981911/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jun 1, 1998
Decision date	Nov 12, 1998
Days to decision	164 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Duncan Hynd Associates, Ltd.**
Location	Teaneck, NJ, US
Contact	DIANA UPTON
510(k) history	2 submissions · 2 cleared · 1998-2000