FDA 510(k) Premarket Notification

K933614 PITUITARY BOARD

CLEARED

Oct 7, 1993
80 days to decision

K933614 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k933614/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 19, 1993
Decision date	Oct 7, 1993
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bionix Development Corp.**
Location	Toledo, OH, US
Contact	RICHARD A WASSERMAN
510(k) history	12 submissions · 12 cleared · 1990-2016