FDA 510(k) Premarket Notification

K100801 PUMA MODEL VERSION 1.0

CLEARED

Jun 18, 2010
88 days to decision

K100801 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k100801/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Mar 22, 2010
Decision date	Jun 18, 2010
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Prowess, Inc.**
Location	Chico, CA, US
Contact	RACHEL SCARANO
510(k) history	9 submissions · 9 cleared · 2003-2023