FDA 510(k) Premarket Notification

K102237 PVS MODEL 1.0

CLEARED

Nov 23, 2010
106 days to decision

K102237 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k102237/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Aug 9, 2010
Decision date	Nov 23, 2010
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Medcom GmbH**
Location	Darmstadt, Hessen, DE
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510(k) history	11 submissions · 11 cleared · 2002-2018