FDA 510(k) Premarket Notification

CLEARED

K012227 MUCHECK - MONITOR UNIT VALIDATION PROGRAM, MODEL V4.1

Oct 1, 2001
77 days to decision

K012227 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k012227/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Jul 16, 2001
Decision date	Oct 1, 2001
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Oncology Data Systems, Inc.**
Location	Oklahoma City, OK, US
Contact	GREGORY G MILLER
510(k) history	4 submissions · 4 cleared · 2001-2010