FDA 510(k) Premarket Notification

K110601 SENTINELLA 102

CLEARED

Mar 18, 2011
16 days to decision

K110601 · Product code: **IYX** · Radiology
Source: https://www.510kdatabase.net/k110601/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Scintillation (gamma) (IYX)
Date received	Mar 2, 2011
Decision date	Mar 18, 2011
Days to decision	16 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	**General Equipment For Medical Imaging, S.A.**
Location	Valencia, ES
Contact	SEVERINE MOINE
510(k) history	3 submissions · 3 cleared · 2009-2023