FDA 510(k) Premarket Notification

K132092 ESTEYA

CLEARED

Sep 26, 2013
83 days to decision

K132092 · Product code: **JAD** · Radiology
Source: https://www.510kdatabase.net/k132092/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Therapeutic, X-ray (JAD)
Date received	Jul 5, 2013
Decision date	Sep 26, 2013
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nucletron B.V.**
Location	Rice Lake, WI, US
Contact	LU ANNE JOHNSON
510(k) history	11 submissions · 11 cleared · 2013-2025