CLEARED

Dec 4, 2015
109 days to decision

K152321 kVue Encompass SRS Insert (Encompass Insert), Encompass SRS Standalone (Encompass Device), Encompass SRS MRI Immobilization device (Encompass MRI Device, Encompass Intracranial Fibreplast Variable Perf Head Only Open View System, Encompass Intracranial Fibreplast Variable Perf Head Only Open View with 119 mm opening

K152321 · Product code: **IYE** · Radiology
Source: https://www.510kdatabase.net/k152321/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Aug 17, 2015
Decision date	Dec 4, 2015
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Qfix**
Location	Avondale, PA, US
Contact	NADIA SOOKDEO HARHEN
510(k) history	7 submissions · 7 cleared · 2015-2023