FDA 510(k) Premarket Notification

K222639 VHA Radiotherapy Bolus

CLEARED

Nov 4, 2022
64 days to decision

K222639 · Product code: **IXI** · Radiology
Source: https://www.510kdatabase.net/k222639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Block, Beam-shaping, Radiation Therapy (IXI)
Date received	Sep 1, 2022
Decision date	Nov 4, 2022
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vha Dean**
Location	Washington, DC, US
Contact	Beth Ripley
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Lg Strategies, LLC**
Contact	Laura Gilmour

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov