FDA 510(k) Premarket Notification

K222803 Oncospace

CLEARED

Feb 2, 2023
139 days to decision

K222803 · Product code: **MUJ** · Radiology
Source: https://www.510kdatabase.net/k222803/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Planning, Radiation Therapy Treatment (MUJ)
Date received	Sep 16, 2022
Decision date	Feb 2, 2023
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oncospace, Inc.**
Location	Baltimore, MD, US
Contact	Sigrid Schoepel
510(k) history	3 submissions · 3 cleared · 2021-2025