FDA 510(k) Premarket Notification

K233698 True Enhance DL

CLEARED

Apr 11, 2024
146 days to decision

K233698 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k233698/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 17, 2023
Decision date	Apr 11, 2024
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Healthcare Japan Corporation**
Location	Hino-Shi, Tokyo, JP
Contact	Laura Turner
510(k) history	10 submissions · 10 cleared · 2011-2026