FDA 510(k) Premarket Notification

CLEARED

K222222 Artemis, Artemis TPO, Artemis MX

Oct 12, 2023
444 days to decision

K222222 · Product code: **QTZ** · Radiology
Source: https://www.510kdatabase.net/k222222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Ablation Therapy Planning And Evaluation (QTZ)
Date received	Jul 25, 2022
Decision date	Oct 12, 2023
Days to decision	444 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eigen**
Location	Nevada City, CA, US
Contact	William Mandel
510(k) history	16 submissions · 16 cleared · 1988-2023