FDA 510(k) Premarket Notification

K240841 Digital Radiography System (ManntiX B, ManntiX K)

CLEARED

Dec 9, 2024
257 days to decision

K240841 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k240841/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Mar 27, 2024
Decision date	Dec 9, 2024
Days to decision	257 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Browiner Tech Co., Ltd.**
Location	Shenzhen, CN
Contact	Li Chen
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Hlongmed Biotech Company**
Contact	Long Yang

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