FDA 510(k) Premarket Notification

K212080 Imaging Plate Scanner, i-Scan

CLEARED

Sep 27, 2021
87 days to decision

K212080 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k212080/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jul 2, 2021
Decision date	Sep 27, 2021
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Guilin Woodpecker Medical Instrument Co., Ltd.**
Location	Flintville, TN, US
Contact	Xunxian Wu
510(k) history	14 submissions · 14 cleared · 2006-2025

REGULATORY CONSULTANT

Consulting firm	**Irc**
Contact	Charles Mack

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