FDA 510(k) Premarket Notification

K220423 PAPAYA & PAPAYA Plus

CLEARED

May 19, 2022
94 days to decision

K220423 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k220423/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Feb 14, 2022
Decision date	May 19, 2022
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Genoray Co., Ltd.**
Location	Flintville, TN, US
Contact	Jiyeon Lee
510(k) history	24 submissions · 24 cleared · 2007-2026

REGULATORY CONSULTANT

Consulting firm	**Genoray America, Inc.**
Contact	Kaitlynn Min

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