FDA 510(k) Premarket Notification

K232158 GenX-CR

CLEARED

Sep 13, 2023
55 days to decision

K232158 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k232158/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jul 20, 2023
Decision date	Sep 13, 2023
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Genoray Co., Ltd.**
Location	Flintville, TN, US
Contact	Inyoung Kim
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

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Device record: https://www.510kdatabase.net/k232158/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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