FDA 510(k) Premarket Notification

K232085 DVAS (DVAS-M, DVAS-W)

CLEARED

Dec 8, 2023
148 days to decision

K232085 · Product code: **EHD** · Radiology
Source: https://www.510kdatabase.net/k232085/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jul 13, 2023
Decision date	Dec 8, 2023
Days to decision	148 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