

K232085 DVAS (DVAS-M, DVAS-W)Dec 8, 2023
148 days to decisionK232085 · 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](https://accessdata.fda.gov)

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