

K032355 ORTHORALIX 9200 DDE, ORTHORALIX 9200 DDE PLUS CEPH, MODELS 5105 0161WW, 5105 0181WW

Sep 25, 2003
57 days to decision

K032355 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k032355/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jul 30, 2003
Decision date	Sep 25, 2003
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply Gendex
Location	Des Plaines, IL, US
Contact	JOHN R MILLER
510(k) history	1 submissions · 1 cleared · 2003-2003

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k032355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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