

K980543 DENOPTIX BARRIER ENVELOPE (SIZE 0-4)Apr 14, 1998
61 days to decisionK980543 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k980543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Feb 12, 1998
Decision date	Apr 14, 1998
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply Intl.
Location	Walker, MI, US
Contact	DANIEL P MURPHY
510(k) history	279 submissions · 279 cleared · 1976-2013

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