

**K012355 IMAGE-X SYSTEM**Aug 9, 2001  
15 days to decisionK012355 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k012355/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jul 25, 2001
Decision date	Aug 9, 2001
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Tg Group, Inc.</b>
Location	Mississauga, Ontario, CA
Contact	WAYNE LEBEAU
510(k) history	1 submissions · 1 cleared · 2001-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012355/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 19, 2026