

K160458 BI IMAGE-X EVOLUTIONJun 20, 2016
122 days to decisionK160458 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k160458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Feb 19, 2016
Decision date	Jun 20, 2016
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radiotecnologia Industrial S.A. DE C.V.
Location	Ixtapaluca, MX
Contact	Marcelo Mojica
510(k) history	1 submissions · 1 cleared · 2016-2016

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