

K120335 EMBRACE THERMOPLASTICMay 3, 2012
90 days to decisionK120335 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k120335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Feb 3, 2012
Decision date	May 3, 2012
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionix Development Corp.
Location	Toledo, OH, US
Contact	JAMES HUTTNER M.D., PH.D.
510(k) history	12 submissions · 12 cleared · 1990-2016

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