

K153270 TruGuard Custom Tongue and Jaw PositionerMar 8, 2016
117 days to decisionK153270 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k153270/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Nov 12, 2015
Decision date	Mar 8, 2016
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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