

**K170521 TRINITY/3D PROSTATE SUITE**May 30, 2017  
97 days to decisionK170521 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k170521/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Feb 22, 2017
Decision date	May 30, 2017
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Koelis</b>
Location	La Tronche, FR
Contact	Laetitia GERVAIS
510(k) history	7 submissions · 7 cleared · 2010-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170521/> 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 16, 2026