

**K160357 TRINITY**May 2, 2016  
84 days to decisionK160357 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k160357/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received         | Feb 8, 2016                                       |
| Decision date         | May 2, 2016                                       |
| Days to decision      | 84 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/k160357/> 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