

**K131448 3D PROSTATE SUITE 3DTRUS PROSTATE MAPPING,
MRI/3DTRUS FUSION OPTION, SECOND LOOK 3DTRUS
FUSION OPTION**Jul 26, 2013
67 days to decisionK131448 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k131448/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 20, 2013
Decision date	Jul 26, 2013
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Koelis
Location	La Tronche, FR
Contact	LAETITIA GERVAIS
510(k) history	7 submissions · 7 cleared · 2010-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131448/> Data sourced from FDA 510(k) public records (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. - Generated May 16, 2026