

K171040 Reusable guides ranges (PERINE range, NAIL range, CON-LEAD range and LIN-LEAD range) and STEADY PRO range

Jul 31, 2017
116 days to decision

K171040 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k171040/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Apr 6, 2017
Decision date	Jul 31, 2017
Days to decision	116 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.net

Device record: <https://www.510kdatabase.net/k171040/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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