

K180970 Disposable guides KDNG00Jul 10, 2018
88 days to decisionK180970 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k180970/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Apr 13, 2018
Decision date	Jul 10, 2018
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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