

K191491 EZ-CoverJun 5, 2020
366 days to decisionK191491 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k191491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Jun 5, 2019
Decision date	Jun 5, 2020
Days to decision	366 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Medxpress.Pro
Location	Leuven, BE
Contact	Katherine Hughey
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Lean TO Quality, LLC
Contact	Jeff Kasoff

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191491/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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