

K211969 EMM Ultrasonic Transducer CoverAug 13, 2021
50 days to decisionK211969 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k211969/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Jun 24, 2021
Decision date	Aug 13, 2021
Days to decision	50 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exact Medical Manufacturing
Location	Lancaster, NY, US
Contact	Ryan Power
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Global Quality and Regulatory Services
Contact	Abdel B Halim

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

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