FDA 510(k) Premarket Notification

CLEARED

K222460 Intraoperative Ultrasound Probe Cover

May 12, 2023
270 days to decision

K222460 · Product code: **ITX** · Radiology
Source: https://www.510kdatabase.net/k222460/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Aug 15, 2022
Decision date	May 12, 2023
Days to decision	270 days
Third-party review	No
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	**Emma International Consulting Group**
Contact	Madison Wheeler

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