FDA 510(k) Premarket Notification

CLEARED

K241872 Remanufactured EndoWrist ProGrasp Forceps (420093)

Nov 7, 2024
133 days to decision

K241872 · Product code: **QSM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241872/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument, Remanufactured (QSM)
Date received	Jun 27, 2024
Decision date	Nov 7, 2024
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rebotix**
Location	St. Petersburg, FL, US
Contact	Chris Gibson
510(k) history	5 submissions · 5 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Ajw Technology Consultants, Inc.**
Contact	Ryan Burke

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