FDA 510(k) Premarket Notification

CLEARED

K250539 Remanufactured EndoWrist Tenaculum Forceps (420207)

Aug 19, 2025
176 days to decision

K250539 · Product code: **QSM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k250539/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument, Remanufactured (QSM)
Date received	Feb 24, 2025
Decision date	Aug 19, 2025
Days to decision	176 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