

K243789 LIBERTY Endovascular Robotic System (LIBERTYOS)Sep 4, 2025
269 days to decisionK243789 · Product code: **DXX** · Cardiovascular
Source: <https://www.510kdatabase.net/k243789/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Catheter Control, Steerable (DXX)
Date received	Dec 9, 2024
Decision date	Sep 4, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Microbot Medical , Ltd.
Location	Yokneam, IL
Contact	Noa Ofer
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells
Contact	Lina Kontos

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT06141694****Assessment of Clin. Capabilities of LIBERTY® Endovascular Robotic System's Performance & Safety in Periph. Vasc. Interv.**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	20 patients (actual)
Study sites	3 sites
Condition studied	Peripheral Vascular Interventions
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Oct 15, 2024
Sponsor	Microbot Medical, INC (Industry)

Primary outcome

Effectiveness Endpoint

Secondary outcome

Safety Endpoint

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06141694