FDA 510(k) Premarket Notification

K251111 Cary

CLEARED

May 7, 2025
26 days to decision

K251111 · Product code: **JCX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k251111/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Suction, Ward Use, Portable, Ac-powered (JCX)
Date received	Apr 11, 2025
Decision date	May 7, 2025
Days to decision	26 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Excitus AS**
Location	Stavanger, NO
Contact	Øystein Refseth
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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