FDA 510(k) Premarket Notification

K242774 SpydrBlade Flex Instrument (PRD-RG1-001)

CLEARED

Jun 6, 2025
266 days to decision

K242774 · Product code: **KNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k242774/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Sep 13, 2024
Decision date	Jun 6, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Creo Medical, Ltd.**
Location	Chepstow, GB
Contact	Diane Davis
510(k) history	10 submissions · 9 cleared · 2017-2025