

**K250725 Hugo™ RAS System**Dec 3, 2025  
268 days to decisionK250725 · Product code: **SCV** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k250725/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Modular Electromechanical Surgical System (SCV)
Date received	Mar 10, 2025
Decision date	Dec 3, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Covidien, LLC</b>
Location	Mansfield, MA, US
Contact	Shriya Kafle
510(k) history	88 submissions · 85 cleared · 2010-2026

**CLINICAL EVIDENCE - NCT05696444**

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**Medtronic Hugo™ Robotic Assisted Surgery (RAS) System in Urologic Surgery (Expand URO)**

Status	Active not recruiting
Enrollment	144 patients (actual)
Study sites	6 sites
Condition studied	Bladder Cancer; Prostate Cancer; Kidney Cancer; Pelvic Tumor; Interstitial Cystitis; Congenital Abnormalities; End Stage Renal Disease; Renal Tumor; Kidney Injury
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 31, 2030
Sponsor	Medtronic - MITG (Industry)

**Primary outcome**

Primary Effectiveness Endpoint - Surgical Success Rate, Defined as the Procedure Not Going Into Conversion

**Secondary outcome**

Secondary Endpoint - Overall Complication Rate From First Incision Through 30 Days Post-procedure.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05696444](https://clinicaltrials.gov/study/NCT05696444)