

K851096 HPU HEAT PROBE AUTOMATED ELECTROCAUTERY SYSTEM

May 22, 1985
64 days to decision

K851096 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k851096/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Mar 19, 1985
Decision date	May 22, 1985
Days to decision	64 days
Third-party review	No

APPLICANT

Company	Olympus Corp.
Location	Mchenry, IL, US
Contact	DAVID BARLOW
Website	https://www.olympus-global.com
510(k) history	142 submissions · 140 cleared · 1978-1995

Olympus Corp. is a Japanese optics and imaging manufacturer founded in 1919. The company operates from McHenry, US, and holds approximately 70 percent of the global endoscope market. Olympus has received FDA 510(k) clearances from total submissions between 1978 and 1995. The company's cleared devices span gastroenterology, urology, obstetrics, gynecology, and chemistry specialties. This regulatory record reflects the company's historical focus on endoscopic surgical instruments and related technologies. Notable cleared device categories include resection electrodes, fiber...

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Device record: <https://www.510kdatabase.net/k851096/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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