

**K894496 OLYMPUS VALVULOTOME W/FIXED TIP**Oct 12, 1989  
85 days to decisionK894496 · Product code: **DWX** · CardiovascularSource: <https://www.510kdatabase.net/k894496/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stripper, Artery, Intraluminal (DWX)
Date received	Jul 19, 1989
Decision date	Oct 12, 1989
Days to decision	85 days
Third-party review	No

**APPLICANT**

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Company	<b>Olympus Corp.</b>
Location	Mchenry, IL, US
Contact	RICK GEOFFRION
Website	<a href="https://www.olympus-global.com">https://www.olympus-global.com</a>
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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