

**K912120 URF-P2**  
**URETERORENOFIBERSCOPE/CHOLEDOCHOFIBERSCOPE**Aug 7, 1991  
85 days to decisionK912120 · Product code: **FBN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k912120/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	May 14, 1991
Decision date	Aug 7, 1991
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Olympus Corp.</b>
Location	Mchenry, IL, US
Contact	DANIEL J DILLON
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...