

K904799 CHF-B20 CHOLEDOCHOSCOPEMar 27, 1991
154 days to decisionK904799 · Product code: **FBN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k904799/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Choledochoscope And Accessories, Flexible/rigid (FBN) |
| Date received | Oct 24, 1990 |
| Decision date | Mar 27, 1991 |
| Days to decision | 154 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Olympus Corp. |
| Location | Mchenry, IL, US |
| Contact | DANIEL J DILLON |
| 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...
